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The new European Regulation 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP Regulation): basic features

Edited by
Paola Di Prospero Fanghella and Ida Marcello

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Preface

The Globally Harmonized Classification and Labelling System (GHS) developed at United Nation level provides a basis for harmonization of rules and regulations on chemicals at national, regional and worldwide level and represents an important factor also to facilitate trade. The new classification, labelling and packaging (CLP) Regulation 1272/2008/EC, entered into force on 20 January 2009, implements in the European Union the system of GHS.

The purpose of CLP Regulation is to ensure a high level of protection of human health and environment as the free movement of substances, mixtures and certain articles. The CLP Regulation will progressively replace and repeal the existing European system in 2015, particularly the Council Directive 67/548/EEC of 27 June 1967 on dangerous substances (DSD) and Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 on dangerous preparations (DPD).

The contemporary implementation of both Regulations represents a challenge for industry and of course for the Competent Authority too, as it is a revolution in the regulatory frame for the management of chemical products all over Europe.

This section of Annali dell'Istituto Superiore di Sanità *will present the main aspects and also some specific issues introduced by the CLP Regulation. The first article is an introduction presenting origin, scope and evolution of CLP Regulation. The second article covers gathering information which represents the first step of classification process when particular attention has to be paid to obtain the information. Another paper reviews the role of the European Chemicals Agency (ECHA) that, founded in 2007, manages the EU REACH Regulation and the new CLP Regulation. An article is dedicated to the application of CLP to nanomaterials, important challenge in the future. CLP is deeply linked with transport in GHS system and therefore an article discusses the relationship among CLP Regulation and transport regulations of dangerous goods. Two papers give an in depth discussion of application of CLP Regulation in Ireland and in Italy. The CLP Regulation requires Member States to establish a national helpdesk to assist the enterprises involved. The ISS Italian CLP helpdesk is settled at the Istituto Superiore di Sanità and the last article describes its way of functioning and also reports some analysis of the number and typology of inquiries received during the last year of activity.*

Thanks to Roberto Binetti, former director of the National Center for Chemical Substances, who contributed from the beginning to the development of both REACH and CLP Regulations at European level. He also gave his valuable support to their implementation in Italy through many activities in the field of chemical substances. This monograph benefited greatly from the experience and know-how he transmitted to some of the authors.

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The CLP Regulation: origin, scope and evolution

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Summary. The CLP Regulation implements in the EU the UN Globally Harmonised System of Classification and Labelling applying the "building block approach", that is taking on board the hazard classes and categories which are close to the existing EU system in order to maintain the level of protection of human health and environment. This Regulation applies to all substances and mixtures placed on the market and besides to classification, packaging and labelling it provides for the notification of the classification and labelling of substances to the Classification & Labelling Inventory established by ECHA. It came into force on 20 January 2009 but a transitional period is foreseen until 1 June 2015 for the full application. At the end of this period the "substance" and "preparation" Directives (respectively 67/548/EEC and 99/45/EC) will be repealed.

Key words: GHS, CLP, classification and labelling, C&L Inventory, CLP helpdesk, CLP notification.

Riassunto *(Il Regolamento CLP: origine, scopo ed evoluzione)*. Il Regolamento CLP traspone nell'Unione Europea il sistema armonizzato globale delle Nazioni Unite applicando il criterio del *building block approach* che consente di adottare alcune classi e categorie di pericolo simili a quelle preesistenti nell'attuale sistema UE per mantenere il livello attuale di protezione della salute umana e dell'ambiente. Questo Regolamento si applica a tutte le sostanze e miscele immesse sul mercato europeo e, oltre alla classificazione, imballaggio ed etichettatura, richiede la notifica della classificazione all'Inventario delle Classificazioni dell'ECHA. Il CLP è entrato in vigore il 20 gennaio 2009, ma prevede un periodo di transizione, fino al 1 giugno 2015 per la piena applicazione. Alla fine di tale periodo le Direttive sulle sostanze e sui preparati (67/548/CEE e 99/45/CE) saranno abrogate.

Parole chiave: GHS, CLP, classificazione e etichettatura, Inventario C&L, CLP helpdesk, CLP notifica.

ORIGIN

The EC Regulation 1278/2008 on classification, labelling and packaging of substances and mixtures, also called CLP [1], establishes a new system on classification and labelling of hazardous substances and mixtures by implementing in the EU the Globally Harmonised Classification and Labelling System (GHS) developed by the United Nations Economic and Social Council (UN ECOSOC) [2].

The purpose of GHS is to define the hazards of chemicals connected to the physical, toxicological and ecotoxicological properties of the substances. It is developed in order to apply agreed criteria to classify chemicals based on their hazardous effects and to communicate hazard information on labels and Safety Data Sheets (SDS).

The most relevant international organizations in the field of classification and labelling of chemicals started to be involved in the early fifties and the work was completed by technical focal points: the International Labour Organization (ILO); the Organization for Economic Cooperation and Development (OECD); and the United Nations Economic and Social Council's Sub-Committee of Experts on the Transport of Dangerous Goods (UNSCETDG).

The United Nations Conference on Environment and Development (UNCED), has adopted on June 1992, at Rio de Janeiro, Brazil, in the Agenda 21 (Chapter 19) regarding the environmentally sound management of toxic chemicals, the need to harmonize the classification and labelling of chemicals as one of the six action programmes to be carried on by the year 2000.

The UN Committee of Experts for the Transport of Dangerous Goods and the Globally Harmonized System of Classification and Labelling of Chemicals formally adopted the GHS in December 2002.

The first edition of the GHS was published in December 2003 and is has been revised every two years and the most updated version is the third revised edition which was published on July 2009.

The GHS document is known informally as *The purple book* and it is made of four parts: an introduction which outlines the scope, the definitions and the hazard communication elements; the classification criteria for physical chemical hazards; the classification criteria for health hazards; and the classification of environmental hazards.

The process of harmonization started looking for common elements in existing systems/recommenda-

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tions/legislation in force in different countries and international/intergovernmental organizations and four major systems were identified:

- the European Union (EU) Directives 67/548/EEC [3] and 99/45/EC [4] for classification an labelling respectively of substances and preparations;
- the requirements of systems in the United States of America for the workplace, consumers and pesticides;
- the requirements of Canada for the workplace, consumers and pesticides;
- the United Nations Recommendations on the transport of dangerous goods.

The entire system was developed taking into account, among others, some basic agreed principles:

- the level of protection of workers, consumers, general public and the environment was not lowered;
- the classification and consequent labelling principles are based on hazards arising from the intrinsic properties of chemical substances and mixtures;
- transitional measures are foreseen in order to implement the globally harmonized new system adopting the required changes in the existing systems.

As a result the aim of GHS is to improve chemical safety and health protection giving reliable and comprehensive information on hazards and protective measures to be adopted through labelling and safety data sheets and also trade in chemicals is expected to be easier.

SCOPE

The CLP Regulation takes on board these principles applying the "building block approach". According to this principle GHS may be seen as a collection of building blocks, the various hazard classes and categories, from which to form a regulatory approach in the different countries and/or systems. For example while physical hazards are relevant in the workplace and transport sectors, consumers may not need to know some physical hazard related to different uses not intended for them.

The CLP Regulation implements hazard end points that are in the GHS in a consistent way. For instance if a substance presents reprotoxic properties the harmonized criteria and labelling should be followed. Additional hazard classes and consequent statements are provided by CLP (EUHxxx) for the end points which are not covered by GHS, but already existing in the EU Directives on classification and labelling of dangerous substances and preparations.

The objective of CLP is to give the criteria to be followed to identify and evaluate the properties of substances and mixtures which lead to a classification as hazardous and to a proper communication of these hazards.

Chemical products have to be classified and labelled by the manufacturers, importers, downstream users or distributors responsible for marketing using harmonised classifications, which are determined at Community level and/or self-classification under their responsibility.

Harmonised classifications of substances are based on Member State proposals or proposals made by manufacturers, importers or downstream users. Mixtures will always have to be self-classified.

CLP is made of seven titles and seven annexes as it is shown below:

Legal text containing principles and general rules

Title I	General issues
Title II	Hazard classification
Title III	Hazard communication in the form of labelling
Title IV	Packaging
Title V	Harmonisation of classification and labelling of substances and the classification and labelling inventory
Title VI	Competent authorities and enforcement
Title VII	Common and final provisions.

Annexes on technical details

Annex I	Classification and labelling requirements for hazardous substances and mixtures
Annex II	Special rules for labelling and packaging of certain substances and mixtures
Annex III	List of hazard statements, supplemental hazard information and supplemental label elements
Annex IV	List of precautionary statements
Annex V	Hazards pictograms
Annex VI	Harmonised classification and labelling for certain hazardous substances
Annex VII	Translation table from classification under Directive 67/548/EEC to classification under this Regulation.

FIELD OF APPLICATION

This Regulation applies to production and use of chemicals not linked to the quantities which are produced or imported per year.

CLP applies to all substances and mixtures (included plant protection product and biocides) placed on the market and to all substances subject to 1907/2008 Regulation on the registration, evaluation, authorization and restriction of chemicals (REACH), even those not placed on the market if they are subject to registration or notification under REACH.

CLP doesn't apply to the transport of dangerous goods, but ensures consistency to them, being the criteria for classification for common end-points the same in the two systems. It applies also to articles containing explosive substances which need to be classified and labelled as explosive.

The exemptions are:

- radioactive substances and mixtures;
- certain substances and mixtures which are subject to customs supervision;
- non-isolated intermediates;
- certain substances and mixtures for scientific research and development;
- waste; and
- certain substances or mixtures in the finished state,

intended for the final user: medicinal products, veterinary medicinal products, cosmetic products, medical devices, food or feeding stuffs.

TIMELINES

CLP came into force on 20 January 2009. There are some transitional provisions for substances/mixtures already placed on the market. A transitional period is foreseen, so that substances are required to be classified, labelled and packaged starting from 1 December 2010, while mixtures from 1 June 2015 according to the provisions of CLP. At the end of the transitional period both 67/548/EEC Directive on dangerous substances and 1999/45/EC Directive on dangerous preparations will be repealed *(Figure 1)*.

CLP has been adapted to the technical progress the first time by the Regulation 790/2009 [8] which entered into force on 25 September 2009.

It transfers the 30th and 31st ATPs (adaptation to technical progress) of Directive 67/548/EEC to the Regulation (EC) n. 1272/2008. The harmonised classifications set in the 1st ATP have been applied, together with related labelling and packaging provisions, since 1 December 2010.

On 30 March 2011 the 2nd adaptation to the technical progress of the CLP Regulation has been published in the EU Official Journal [9]. It entered into force on 19 April 2011 and mainly adapts the CLP to the 3rd revision of the GHS and will apply to substances from 1 December 2012 and to mixtures from 1 June 2015.

NOTIFICATION

CLP provides for the notification of the classification and labelling of substances to the Classification & Labelling Inventory (C&L) established by European Chemicals Agency (ECHA). Manufacturers or importers of substances subject to registration, under Article 6 of the REACH Regulation, or classified as hazardous, irrespective of the quantity, need to be notified to the inventory both whether they are put on the market as such or in a mixture which is classified as hazardous due to the presence of this substance. Also substances in articles which are subject to registration under Article 7 of the REACH Regulation are required to be notified to the ECHA Inventory.

This Inventory will be maintained by ECHA and a non-confidential version of it will be published on the ECHA website.

CRITERIA

Translation tables

CLP classification criteria for substances are very similar to the pre-existing EU Directives criteria. Translation of existing classifications into CLP classifications is made easier by means of a translation table in Annex VII to this Regulation according to the CLP Article 61 [5]. These CLP classifications are to be considered as minimal classifications and needs to be used with care as there are limitations to the applicability for some types of hazards.

This table was also used as a basis for the semi-automatic transposition of existing Annex I entries (updated to the 29th ATP) to the table 3.1 of Annex VI of the CLP Regulation.

For physical chemical properties experts were consulted when the classification according to CLP criteria and that according to transport Regulation were not the same.

When a substance is not present in Annex VI to CLP with the harmonized classification, it has to be self-classified by the responsible for marketing. In addition, also substances which are in Annex VI have to be self classified by the manufacturer/importer for the end points which are non classified for.

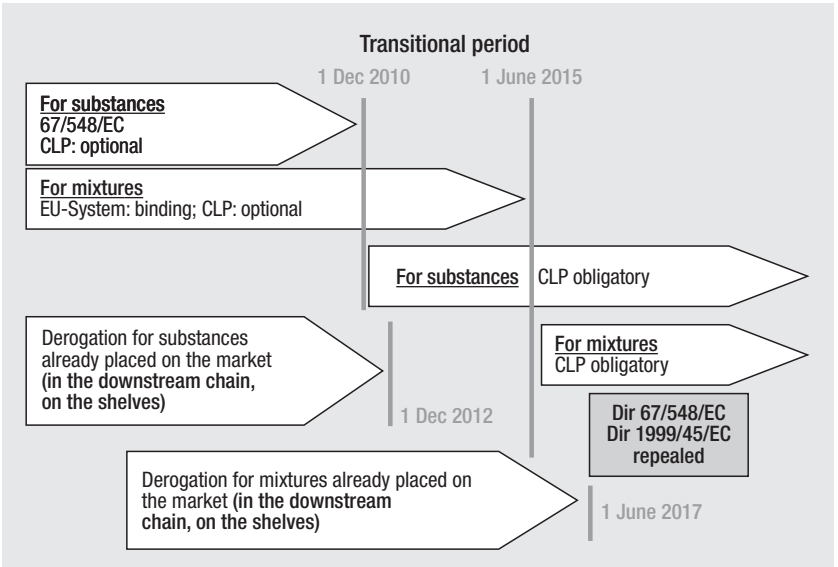

Fig. 1 | *Timelines for the application of the CLP Regulation*

As the entire Annex I to DSD list of substances, as amended by the 29th ATP, was transposed into the CLP Annex VI, the chance was taken to remove all the specific concentration limits which were identical to the generic concentration limits.

A number of errors in the translation of Annex VI has also been identified, and will be addressed in future updates to CLP. In the meantime, the list of known errors can be found on the ECHA website.

Information requirements

If the information available is not sufficient to conclude on the hazardous properties of the substance, new testing must be performed to determine the physical hazards of a substance if required in CLP Annex I, part 2, while new tests can be performed for the determination of the health and environmental hazards of the substance, but they are not obligatory under CLP.

On the other side REACH requires for filling data gaps for substances under registration, so that these new data can be used to classify under CLP.

Registrants have the obligations to avoid unnecessary new animal studies sharing test data each other or using alternative and non-test methods to assess the properties of chemical substances [5].

Information that has been used for the classification and labelling of substances or mixtures must be kept available for at least 10 years after the last supplying in order to be checked, if necessary, by competent authorities.

SOME CHANGES IN THE CRITERIA

Hazard classes and categories

Classification criteria for physical hazards, health and environmental effects are reported in Annex I and some changes have occurred implementing the new system: for physical hazards five hazard classes under Directive 67/548/EEC are extended to sixteen hazard classes under CLP Regulation; for health hazards two new classes were adopted, the single exposure specific target organ toxicity (STOT-SE) and the repeated exposure specific target organ toxicity (STOT-RE).

Environmental hazards

Classification criteria for environmental effects are slightly different from the existing ones: BCF cut-offs ≥ 500 instead of currently ≥ 100 and log Kow ≥ 4 instead of currently ≥ 3.

As a consequence some substances currently classified as R 50/53 ("Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment") or R 51/53 ("Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment") would fall into a lower category or would not be classified at all, so that substances to which the currently applied R53 ("May cause long-term adverse effects in the aquatic environment") is based on a BCF between 100 and 500 and/or a log Kow between 3 and 4 need to be re-evaluated as classification could change.

Classification of mixtures

The innovative tiered approach for the classification of mixtures in the case of health acute toxicity is based on three steps: classification based on testing of the mixture, on bridging principles, on the concentrations and toxicities of the ingredients (ATE values using ATEmix calculations).

Some changes in the classification of mixtures are due to the generic concentration limits for reprotoxicants which are lowered to 0.3% for reprotoxicity category one and two and to 3.0% for category three, while in the existing system the values were 0.5% and 5.0% respectively.

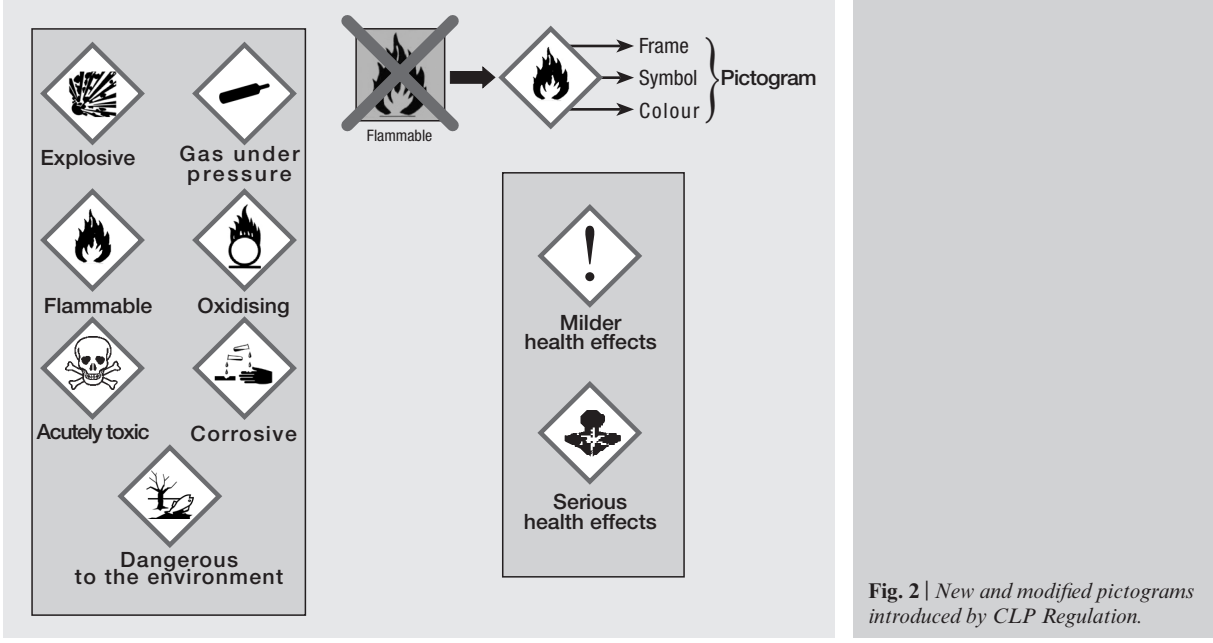

Fig. 2 | *New and modified pictograms introduced by CLP Regulation.*

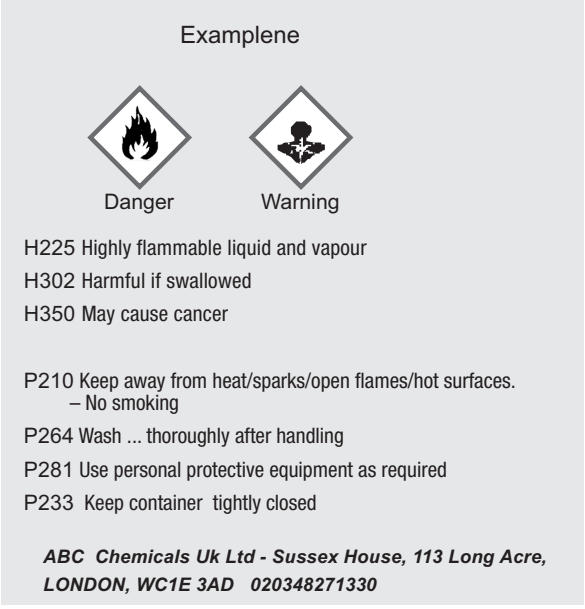

Fig. 3 | *Labelling elements: an example of label.*

Also for skin irritants the concentration limits are lowered from 10% to 5%.

As a consequence, a certain number of mixtures which are not classified according to the existing system need to be classified according to CLP.

Labelling

According to CLP hazard pictograms (symbols) are diamond shaped, white and black with a red border, mostly similar to the existing EU system, but two new symbols are also adopted, the damaged person for some severe effects and the exclamation mark for some less severe effects *(Figure 2)*.

In addition the indications of danger such as flammable, or irritant are replaced by two new signal words, "danger" and "warning" while risk and safety phrases are replaced by hazard statements respectively. No more than six P statements should appear on the label while hazard statements are selected following some priority criteria in the case of a resulting too high number of statements.

New phrases for the different hazards are introduced too. Hazard statements replace R-phrases, while Precautionary statements replace S-phrases.

According to CLP Article 17, a substance or mixture classified as hazardous shall bear a label including the following elements:

- name, address and telephone number of the supplier(s);
- the nominal quantity of the substance or mixture in the package where this is being made available to the general public, unless this quantity is specified elsewhere on the package;
- product identifiers;
- hazard pictograms;
- the relevant signal word;
- hazard statements;
- appropriate precautionary statements;
- a section for supplemental information.

An example of label is shown in *Figure 3*.

INFORMATION RELATING TO EMERGENCY HEALTH RESPONSE

The provisions in CLP Article 45 are similar to the provisions of the dangerous preparation directive (Article 17) asking to the Member States to appoint body(s) responsible for receiving information on mixtures classified as hazardous on the basis of their health or physical effects to be used for medical purposes, in particular in event of emergency. Information must be kept confidential.

In addition to that, "by January 2012, the Commission shall carry out a review to assess the possibility of harmonising the information..., including establishing a format for the submission of information by importers and downstream users to appointed bodies". As a consequence Member States and Commission are evaluating the possibilities to establish a harmonised format for submission of information.

HELPDESK

CLP provides for the establishment of national helpdesks in order to provide advice to companies on the CLP obligations. All the helpdesks are connected in the joint network of REACH and CLP helpdesks settled at ECHA. The Italian CLP helpdesk is located at the Istituto Superiore di Sanità which is the technical support to the national Competent Authority.

DOWNSTREAM LEGISLATIONS

There are a lot of obligations in Community legislation referring to C&L, so that EU and national legislation need updating to adopt CLP, *e.g.* workers safety and consumer products Directives, Seveso Directive and others. Some updating has been already made for detergents Regulation, toys and cosmetics Directives and some others are in progress.

EVOLUTION

The simultaneous application of CLP and REACH Regulations is in a certain way a revolution in the management and control of chemicals. The aim is to know as much as possible the properties and the risks related to substances and mixtures to which humans and environment can be exposed. The adoption of adequate measures to minimize risks is the natural consequence of this new policy.

In addition to many guidance on REACH application also some guidance for CLP application were published by ECHA: the Introductory guidance on CLP Regulation and Guidance on the application of the CLP criteria [6, 7].

The CLP Regulation is going to be adapted to the technical progress the third time by end 2011 in order to include harmonized classifications for substances evaluated by the RAC Committee by end 2010.

In the meantime the UN GHS is being revised for the fourth time in the next biennium and ClP will be adapted again.

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Conflict of interest statement

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Information gathering for CLP classification

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Summary. Regulation 1272/2008 includes provisions for two types of classification: harmonised classification and self-classification. The harmonised classification of substances is decided at Community level and a list of harmonised classifications is included in the Annex VI of the classification, labelling and packaging Regulation (CLP). If a chemical substance is not included in the harmonised classification list it must be self-classified, based on available information, according to the requirements of Annex I of the CLP Regulation. CLP appoints that the harmonised classification will be performed for carcinogenic, mutagenic or toxic to reproduction substances (CMR substances) and for respiratory sensitisers category 1 and for other hazard classes on a case-by-case basis. The first step of classification is the gathering of available and relevant information. This paper presents the procedure for gathering information and to obtain data. The data quality is also discussed.

Key words: hazardous substances, European Union, information systems, classification, globally harmonized system.

Riassunto *(Raccolta di informazioni per la classificazione in accordo con il Regolamento CLP)*. Il Regolamento sulla classificazione, etichettatura e imballaggio di sostanze e miscele (CLP) considera due tipi di classificazione: la classificazione armonizzata e l'autoclassificazione. La classificazione armonizzata è decisa a livello comunitario e l'Allegato VI del Regolamento CLP contiene un elenco di classificazioni armonizzate. Le sostanze per cui non è disponibile una classificazione armonizzata devono essere autoclassificate dal responsabile della loro immissione sul mercato, sulla base delle informazioni disponibili e secondo i criteri contenuti nell'Allegato I del CLP. Il CLP stabilisce che la classificazione armonizzata verrà effettuata per cancerogeni, mutageni, tossici per la riproduzione (sostanze CMR) e sensibilizzanti respiratori di categoria 1 e per altre classi di pericolo individuate caso per caso. La raccolta di dati pertinenti disponibili rappresenta la prima fase del processo di classificazione. Questo articolo illustra la procedura per la raccolta di dati e come recuperare informazioni. Vengono inoltre esaminati aspetti relativi alla qualità dei dati.

Parole chiave: sostanze pericolose, Unione Europea, sistemi informativi, classificazione, sistema armonizzato globale.

INTRODUCTION

In the framework of Regulation (EC) no. 1272/2008 [1] (named CLP Regulation - classification, labelling and packaging), the information gathering on chemicals is mainly required by the self-classification principle. This principle, defined as *Obligation to carry out investigations*, was originally in the Article 6 of Directive 67/548/EEC [2]. The CLP Regulation reaffirmed the self-classification principle in Article 55, comma 4, as *Obligation to carry out investigation (Table 1)*.

HARMONISED AND SELF- CLASSIFICATIONS UNDER DIRECTIVE 67/548/EEC

Two different types of classification were foreseen for substances before the CLP Regulation:

- the *harmonised classification*, intended to address all the physicochemical, toxicological and ecotoxicological properties of substances and preparations which may constitute a risk during normal handling or use. It was determined at Comunitary level and was the outcome of an in-depth evaluation made by an EU Working Group of Experts (European Commission Working Group on the Classification and Labelling of Dangerous Substances), taking account of all the information available on the intrinsic properties of a substance (physicochemical, toxicological and ecotoxicological);
- the *self-classification* (or *provisional classification*), produced by the responsible for marketing those substances not included in the list of harmonised classifications but presenting anyway dangerous properties.

However, in some cases the harmonised classification was *partial* as it was addressed only to a selected hazard class; a specific *note H* was applied to these cases. The note H indicates that the classification given was only related to the dangerous property(ies) indicated by the risk phrase(s) in combination with the category(ies) of danger shown in the classification itself, and thus other hazards not included in the harmonised classification need to be addressed by the supplier of the chemical [3]. Until 2008 the partial harmonised classification regarded only specific sub-

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Table 1 | *Self-classification principle [1, 2]*

Previous legislation Directive 67/548/EEC – Article 6	New legislation Regulation 1272/2008 – Article 55(4)
Obligation to carry out investigations Manufacturers, distributors and importers of dangerous substances which appear in the EINECS but which have not yet been introduced into Annex I shall be obliged to carry out an investigation to make themselves aware of the relevant and accessible data which exist concerning the properties of such substances. On the basis of this information, they shall package and provisionally label these substances according to the rules laid down in Articles 22 to 25 and the criteria in Annex VI.	**Obligation to carry out investigations** […] for manufacturers, distributors and importers of substances which appear in the EINECS but for which no entry has been included in Part 3 of Annex VI to Regulation (EC) No 1272/2008 to carry out an investigation to make themselves aware of the relevant and accessible data which exist concerning the properties of such substances. On the basis of this information, they shall package and provisionally label dangerous substances according to the rules and the classification criteria.

stances or group of substances such as certain complex coal and oil derivatives, and certain entries for groups of substances in Annex I to Directive 67/548/EEC (*e.g.* o-anisidine azodyes and o-tolidine dyes). For example in the case of petroleum derivatives the harmonised classification only addresses the carcinogenic and, in some cases, the aspiration hazards. For these petroleum substances the responsible for placing on the market have to carry out the self-classification for all other hazards, not included in their respective Annex I entries, based on the available data (*i.e.* flammability, health systemic effects and environmental hazards).

The self-classification was always required for preparations.

PARTIAL HARMONISED CLASSIFICATION UNDER CLP REGULATION

The Regulation 1272/2008, like the previous system, maintains the two different approaches to the classifications: *harmonised classification* laid down at Community level according to the classification criteria set out in Part 2-5 of Annex I to CLP and *self-classification* to be produced by the supplier through the application of the same above mentioned criteria and on the basis of available data.

The innovative principle set out by the CLP Regulation is that in the future the harmonised classification will predominantly focus on:

- substances of high concern such as carcinogens, germ cell mutagens, substances toxic for reproduction (CMRs) and respiratory sensitisers (Article 36.1 of the CLP Regulation). This limitation is due to the fact that Authorities' resources should be focused on the most and relevant hazardous properties for which expert judgment is required and for which classification gives rise to important risk management measures [4];
- moreover, harmonised classification will normally cover all hazardous properties for active substances in biocidal products (regulated under Directive 98/8/EC) and plant protection products (under Regulation 1107/2009/EC) (Article 36.2 of the CLP Regulation);
- other hazard classes or differentiations, with regard to health and the environment, could also be addressed on a case-by-case basis (*e.g.* in case of contradictory data for particular properties which need an *expert judgment*), if a justification can be provided demonstrating the need for such action at Community level (Article 36.3 of the CLP Regulation). This means that all the other hazards will be self-classified.

It follows that harmonised classification will increasingly be partial and CLP Regulation will be primarily a self-classification system for enterprises. The *Guidance on the application of the CLP criteria* places emphasis on self-classification of the substances or mixtures by manufacturers, importers or dowmstream users defining it a *core principle* [5].

This means that even for substances included in Table 3.1 and Table 3.2 of Annex VI to CLP, these harmonised classifications indicate the *minimum mandatory classification*; all the other endpoints not covered by such classification have to be investigated, searching available information and, in case of relevant data, the self-classification for these endpoints will be performed (as stated by Article 4.3 of the CLP Regulation). For example, a substance may have an harmonised classification for acute oral toxicity, but not for acute dermal toxicity. This means that a supplier would have to explore, using the information available, whether the classification criteria for acute dermal toxicity are fulfilled, and to classify accordingly [6].

The EU Commission Regulation 286/2011, consistently with the new principle regarding the partial harmonised classification introduced by the CLP Regulation, deletes note H from Annex VI [7].

Under CLP Regulation, as in the old legislation, mixtures must always be self-classified.

THE BASIC STEPS OF CLASSIFICATION

The self-classification made by the responsible for the placing on the market should follow the same criteria used by RAC (Risk Assessment Committee) of ECHA (European Chemicals Agency) for harmonised classification, set out in the Annex I to the CLP Regulation and explained in detail in the section 12 of the *Introductory guidance on the CLP Regulation* [8].

The classification process involves the following basic steps:

- gathering of all relevant available data regarding the potential hazards of the substance (or mixture) of interest;

- systematic examination and evaluation of adequacy and reliability of the gathered information to ascertain the hazard associated with the substance (or mixture);
- comparison of the information with the criteria for classification for each hazard class or differentiation within the hazard class (distinction depending on the route of exposure or the nature of the effects) checking if gathered information reveals an hazardous property and if this property is directly comparable to the respective hazard criteria in order to decide if the substance will be classified as hazardous.

It follows from the foregoing that the information gathering represents the first step of the self-classification process.

DATA FOR CLASSIFICATION AND THEIR ORIGIN

The intrinsic properties of chemicals are the information to be searched for every toxicological or ecotoxicological endpoint. Data related to physical properties, if not available in the literature, must be generated by means of experimental assays unless adequate and reliable information are already available (Article 8.2 of

Table 2 | *CLP guidance documents*

Guidance on the preparation of dossiers for harmonised classification and labeling [12]
http://guidance.echa.europa.eu/docs/guidance_document/clh_en.pdf

Language: available only in English

Updating: May 2010

Recipients: for Industry Use (manufacturers, importers and downstream users) and for Authorities Use (Member State Competent Authorities - MSCAs)

The document provides technical guidance for preparing a CLH (harmonised classification and labelling) dossier under the CLP Regulation. It gives an overview of the general process for the preparation of a CLH dossier providing detailed information on the different steps in order to prepare a CLH dossier (including the phase of information gathering) and information about the processing of the dossier once it has been submitted to the Agency.

Regarding information gathering the document focuses on additional sources such as:
- *Registration dossiers*: information can be generated as a result of dossier or substance evaluation under the REACH Regulation
- *Other available information*: information required for other regulatory purposes (*e.g.* data submitted under the Plant Protection Products and Biocidal Products Directives); information generated under internationally recognized chemical programmes for example reviews performed under the preceding EU legislation (*e.g.* Regulation (EEC) no. 793/93) by OECD, WHO, IARC, ECETOC, or by Member States
- *Information on related substances and from (Q)SARs:* information on structural analogues
- *Data on substances undergoing new testing*: for example as a consequence of a testing proposal included in the registration dossier
- *Other supporting information*

Introductory Guidance on the CLP Regulation [8]
http://guidance.echa.europa.eu/docs/guidance_document/clp_introductory_en.pdf

Language: available in all EU languages

Updating: August 2009; a new edition will be released in 2011

Recipients: mainly addressed to suppliers (*i.e.* manufacturers of substances, importers of substances and mixtures, downstream users, distributors of substances and mixtures and producers and importers of certain specific articles).

The document provides guidance on the basic features and procedures of the CLP Regulation. It describes how to carry out the self-classification. Of particular concern for information gathering, as it is focused on where find information in order to classify and label substances and mixtures, are:

Section 10. *Sources of information* and

Annex 3 - *Additional sources* such as:

in-house search

information produced for compliance with REACH

transport directives (substances)

other information sources including:
- EU information and data sources (*e.g.* ESIS- European Chemical Substances Information System and EFSA- European Food Safety Authority, for active substances of plant protection products)
- International non-EU sources: EChem Portal (from OECD), NICNAS (National Industrial Chemicals Notification and Assessment Scheme, Australia), IPCS (International Programme on Chemical Safety on INCHEM website)
- United States sources: Registry of Toxic Effects of Chemical Substances (RTECS) available from the NIOSH-National Institute of Occupational Safety and Health; US Environmental Protection Agency (EPA); IRIS (Integrated Risk Information System) available from the US EPA website; TOXNET (includes databases such as Toxline and HSDB); PubMed portal from the US National Library of Medicine.

Guidance on the Application of Regulation (EC) No 1272/2008 [5]
http://guidance.echa.europa.eu/docs/guidance_document/clp_en.pdf

Language: available only in English

Updating: August 2009; a new edition expected at the end of 2011

Recipients: for Industry Use (manufacturers or importers) and for Authorities Use (Member State Competent Authorities - MSCAs)

The document provides detailed guidance on how to carry out the self-classification: general principles of classification and labelling under the CLP Regulation as well as on the criteria for the classification and labelling of substances and mixtures and how to use relevant available information for classification purposes.

CLP Regulation) whereas it should be noted that the obligation to perform any test with respect to toxicological and ecotoxicological properties is not imposed (Article 8.1 of the CLP Regulation) and classification needs only to be made on the basis of available data.

Relevant data for the purpose of classification of a substance can be gathered by many sources according to a procedure formerly used in the 67/548/EEC Directive, reaffirmed by CLP (Article 5 of the CLP Regulation) and referred substantially to:

- technical and scientific literatures for physical properties;
- human data retrieved from a number of sources including analytical epidemiological studies, clinical studies, well documented case reports and observations; human experience such as occupational data and data from poison information units and accident databases are also taken into account;
- experimental data assays including all *in vitro* and *in vivo* testing data, obtained through standard internationally recognized methods;
- non-testing data (*e.g.* data obtained with (Q)SAR models, grouping of substances, read across, weight of evidence).

The procedure of gathering information needs to be as wide as possible and could include sources of different types such as:

- *open literature information* (primary papers, reviews, books, monographs, and reports of proceedings, meetings and conferences);
- *electronic sources* include factual data banks (containing pre-selected factual information) and bibliographic databases (providing direct access to the literature without any pre-selection and used for exhaustive searches when factual databases contain insufficient data);
- *portals* (allowing simultaneous search of multiple databases);
- *the internet* (search engines allow identification of electronic versions of a wide range of data sources);
- *websites* of various expert organizations and regulatory bodies contain useful information;
- *grey literature*, intending materials that cannot be found easily through conventional channels such as publishers. This unconventional literature includes technical reports from governmental agencies or scientific research groups, working papers from research groups or committees;
- *in house company and trade associations files*, intending unpublished information from companies, may include studies generated in-house, commissioned studies carried out by contract houses, information on type and experience in use, reports from downstream companies and customers, purchased reports from other companies, collections of published papers and reviews of published data, and safety data sheets. This kind of information may be regarded as confidential and require expertise to interpret it;
- any other data that may assist in identifying the presence or absence of hazardous properties of the substance.

Within the human data, the possibly available information on human experience, when adequate, reliable and representative, generally deserves primary attention with respect to animal experiments and testing data. It should be noted that in accordance with the Community institutions' practice, established in Annex VI to Directive 67/548/EEC and reaffirmed in CLP Regulation, information derived from extensive and consistent *practical human experience* may be considered to be sufficiently robust, by an expert judgment, in order to classify (*e.g.* for substances presenting an aspiration hazard in humans or which cause significant/severe inflammation of the skin on immediate, prolonged or repeated contact or which cause significant ocular lesions or capable of inducing a sensitisation by skin contact in a substantial number of persons). A typical example may be methanol, which has an oral LD50 in rat ≥ 5000 mg/kg while from human experience data this substance is known to cause lethal intoxications in humans (mostly via ingestion) in relatively low doses ("…minimal lethal dose in the absence of medical treatment is between 300 and 1000 mg/kg") [5].

Finally, also all previously harmonised classifications under Directive 67/548/EEC, that have been converted into CLP harmonised classification, are sources to be considered. The data source for this harmonised classifications is represented by Table 3.1 (it lists about 8000 substances officially classified by EU according to Directive 67/548/ EEC) and Table 3.2 (it lists the same substances according to CLP classification) of Annex VI to CLP Regulation amended by Regulation 790/2009 and Regulation 286/2011 [7, 9].

In case of substances subjected to registration, for which a dossier is available, the same sources have to be intended as additional sources useful in order to complete the available database.

HOW TO OBTAIN THE INFORMATION

A single exhaustive source of information does not exist because of the extremely numerous and multidisciplinary hazards to be considered for the classification (physical-chemical, health and environmental). CLP Regulation clearly affirms that for purpose of self-classification all *relevant* and *accessible* existing information should be taken into consideration. Data must be *adequate* and *accessible*. The term adequate is used to cover the reliability of the available data and their relevance for human and environmental hazard classification. *Accessible* means that, except for physical hazards for which generally substances and mixtures testing is required, data are not experimentally produced but may be obtained by a relevant scientific searching of all data which are known or which "should reasonably be expected to be known" to whom who have to carry out the self-classification. This definition presently acquires particular importance because of the remarkably high amount of

Table 3 | *REACH guidance documents relevant to CLP*

Guidance on information requirements and chemical safety assessment [13]
http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_en.htm#r20

Language: the pathfinder is available in all EU languages while some parts are available only in english

Updating: May 2008; a new edition will be released in 2011

Recipients: for Industry Use (manufacturers, importers, downstream users) and for Authorities Use (Member State Competent Authorities - MSCAs); addressed to trained persons.

Structure: consists in a package of 28 single documents including a *pathfinder* to the different elements of the guidance and two major parts:
- *Concise guidance*: focus processes and dialogues, made up of seven parts (Part A to G);
- *Reference guidance*: supporting documents containing technical and scientific details of hazard and exposure assessment (Chapters R.2 to R.20).

The guidance document gives advice on how to carry out certain steps which are common to hazard assessment under REACH and classification, where to find available information, how to assess collected data or how to use non-testing information. Expert knowledge may be required to understand and use this advice.
The parts of this Guidance, relevant for information gathering, with purpose of classification are the following:

Concise guidance - Part B: Hazard assessment [14]
http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_part_b_en.pdf?vers=20_10_08

Language: available in all EU languages

Updating: May 2008

Contains concise guidance on hazard assessment including information requirements on intrinsic properties of a substance to be registered under REACH, including information gathering, non-testing approaches and the so-called "integrated testing strategies" in order to generate relevant information for each hazard. Each of the sections in Part B corresponds to the more in-depth guidance contained in Chapters R.2 to R.10. Particularly relevant for information gathering are:

Reference guidance - Chapter R.3: Information gathering [15]
http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_r3_en.pdf?vers=20_08_08

Language: available only in English

Updating: May 2008

This Guidance describes in depth collection of available information; it considers all types and sources of information that could be included in any search strategy (in house Company and trade association files; databanks and databases of compiled data; published literature; internet search engines and relevant websites; (Q)SAR models). Moreover an indicative list of major available databases and databanks is given (in Sections R.3.1 to R.3.4 distinguishing "no fee sources" and "fee based sources". The adequacy and suitability of such data through specific Integrated Testing Strategies (ITS) for each endpoint is given.

Reference guidance - Chapter R.4: Evaluation of available information [16]
http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_r4_en.pdf?vers=20_08_08

Language: available only in English

Updating: May 2008

Provides guidance on how to evaluate all available information gathered; covers concepts of completeness (does the available information meet the information required for classification?) and quality (relevance, reliability and adequacy) of information.

Reference guidance - Chapter R.6: Guidance on QSARs and grouping of chemicals [17]
http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_r6_en.pdf?vers=20_08_08

Language: available only in English

Updating: May 2008

Detailed guidance on non-testing approaches such as QSAR and grouping which facilitate the evaluation of the intrinsic properties of chemicals. Moreover, it provides sources in terms of software programs developed for the calculation of molecular descriptors and pertinent computational tools/databases that are either publicly or commercially available.

Reference guidance - Chapter R.7: Endpoint specific guidance This chapter contains detailed specific guidance on gathering, evaluation and, where necessary, generation of information on the physicochemical properties and the different human health and environmental endpoints which can contribute to derive appropriate information for classification and labelling of a substance. The document is divided in main sections on each endpoint which is described and for which the process of gathering and evaluation of all available data is provided. Each endpoint is described and its importance is explained in the context of human health or environmental fate. Guidance is given on how to evaluate the information that could be available for a given substance; this advice focuses to provide the criteria in order to aid the judgement and ranking of the available data for their adequacy and completeness. Practical tables give references to information sources (hard and electronic databases) for which features and limitations are discussed.

Chapter R.7a - Endpoint specific guidance for physico-chemical properties and the different human health [18]
http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_r7a_en.pdf?vers=02_02_10

Language: available only in English

Updating: May 2008

In this chapter, specific guidance on meeting the information requirements on physicochemical properties and the different human health and the environmental endpoints is presented. The guidance for each specified endpoint has been developed as a stand-alone report addressing the aspects of gathering, evaluation and generation of information. Over 20 intrinsic physicochemical properties (such as melting/freezing point; boiling point; relative density; vapour pressure; surface tension; water solubility; partition coefficient in-octanol/water; flash-point; flammability; explosive properties; self-ignition temperature; oxidising properties; granulometry; stability in organic solvents and identity of relevant degradation products; dissociation constant; viscosity) and individual human health endpoints (such as skin- and eye irritation/corrosion and respiratory irritation; skin and respiratory sensitization; acute toxicity; repeated dose toxicity; reproductive and developmental toxicity; mutagenicity and carcinogenicity) are examined.

Continued

Table 3 | *Continued*

Chapter R.7b - Endpoint specific guidance for environment [19]
(http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_r7b_en.pdf?vers=20_08_08).

Language: available only in English

Updating: May 2008

Are examined environmental endpoints with reference to aquatic toxicity; long-term toxicity to sediment organisms; degradation and biodegradation. Reference to pertinent databases and documents are provided.

Chapter R.7c - Endpoint specific guidance for environment and toxicokinetics [20]
http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_r7c_en.pdf?vers=20_08_08

Language: available only in English

Updating: May 2008

Environmental endpoints with reference to bioconcentration and bioaccumulation; long-term toxicity to birds; effects on terrestrial organisms are examined; an Appendix describes databases on aquatic bioaccumulation. Extensive guidance on toxicokinetic data are moreover given.

scientific information available through the internet. "Reasonably be expected to be known" may includes *e.g.* classifications/evaluations of carcinogenic agents performed by institution such as IARC (International Agency for Research on Cancer) and US EPA (United States Environmental Protection Agency). These classifications, carried out in accordance with clearly specified criteria and procedures, have been always used in accordance with an institution's prior practice for substances not formally classified in Europe under Directive 67/548/EEC [10] (*e.g.* dichlorvos non classified for carcinogenicity under Directive 67/548/EEC but classified by IARC as "probable human carcinogen" group 2B which corresponds to a category 2 carcinogen under CLP Regulation).

Under CLP it is not required to perform animal testing only for the purpose of health and environmental classifications. It is however important to know where to retrieve information relevant for each classification endpoint in order to develop an appropriate searching strategy. The European Chemicals Agency (ECHA) made available a set of tools in order to facilitate the CLP Regulation application; between these a range of guidance documents providing an overall guidance for the classification have been published, freely available to access and download from ECHA's webpage (http://www.echa.europa.eu) and very useful in the phase of information gathering. These guidance documents help the data searchers to understand the range of potential sources of information and their content, structure, design and format. *Table 2* shows some of these relevant documents.

Moreover physical, health and environmental hazard assessments are an important part of the REACH registration process. For this it should be noted that some guidance documents on REACH, produced by ECHA, which describe good practices, processes and methods in order to fulfill obligations compelled by Regulation 1907/2006, are also relevant for CLP Regulation as they contain indication on how to derive adequate information on hazard assessment of substances and mixture. *Table 3* shows some of these REACH guidance documents. These guidance documents generally include methodological sections (instructions useful to set search strategies and evaluate relevancy, reliability and adequacy of the information gathered) and tables which contain a wide selection of free- or against payment information sources and describe characteristics and limits of each source giving direct links.

Following the same principles of REACH Regulation the relevant information used to produce the classification (and the labelling) of substances or mixtures must be assembled and kept available for a period of at least 10 years by the supplier after the last supply of the substance or the mixture together with any other information that suppliers are obliged to hold as specified in Article 49.1 of the CLP Regulation [1]. National Competent Authorities or the Agency (ECHA) may require the supplier to submit this information unless it is already available as part of a registration (under REACH) or a notification (under CLP). This obligation to store data applies not only to data showing that the substance is hazardous, but also to data showing that the substance is not hazardous and therefore *not classified* because it does not meet the classification criteria or is *unclassifiable* due to inconclusive data or lack of data. The principle is that the classification criteria apply to all hazardous and all not hazardous substances and mixtures as reliable data in order to decide on their hazard are needed and either a classification decision or a reason for not classifying must be recorded for each classification endpoint.

SOME CONCLUSIVE OBSERVATIONS

It is not possible to use only one source of information for classification purposes. All the data sources contained in the guidance documents in *Table 2* and *Table 3* represent a good starting point in the step of gathering information, but an integration between the different sources is needed in order to obtain adequate overall data. In particular, account should be taken of their possible limits as, of course, quality and comprehensiveness of these sources are widely different: for example some classification endpoints need high specialization (*e.g.* some data base particularly focused in

aquatic toxicity or in environmental fate). On the other hand the problem regards not only the quality but also the quantity of data contained in the information sources. Some information sources contain a relatively restricted number of chemicals but high quality data in contrast to other sources including a large number of chemicals but low quality data. For example in the case of acute health hazard classification the Registry of toxic effects of chemical substances (RTECS) compiled by NIOSH (National Institute of Occupational Safety and Health) represents the world's most extensive collection of numerical toxicological data as contains more than 160 000 chemicals while Hazardous substance data bank (HSDB) contains over 5000 chemicals. In this case it is important to know that information in HSDB is referenced and peer reviewed by the Scientific Review Panel (SRP), a Committee of experts in the major subject areas within the data bank's scope while for RTECS the editor declares unequivocally that the data are taken from primary source without any evaluation in terms of correctness, validity and quality of the studies. Nevertheless in some cases RTECS is the only available source of data.

Other limits that can be presented by the different sources are due to:

- *type of information used*. For example while using a transport classification for a substance not included in Annex VI to CLP, one should be aware that the transport classification does not include all of the GHS categories for physical, health and environmental hazards, so the absence of a transport classification does not mean that the substance should not be classified under CLP [8];
- *multiple data from different information sources*. In this case data obtained according to validated test methods (specified in Annexes V and VIII of Directive 67/548/EEC, or REACH Annex X methods; or OECD) and/or in compliance with the principles of GLP (good laboratory practice) (or equivalent) standard take precedence. However a certain flexibility in their evaluation is needed: the optimum indeed would be the availability of updated and GLP complying data, but if a study is not conducted in accordance with GLP it does not necessary mean the study is not suitable. An expert judgment could be necessary in these cases [5];
- *conflicting data from different sources, e.g.* from reviews (often acute toxicity data). In this case it is essential to retrieve the original source. It is also necessary in this case to choose reliable data (in accordance with guidelines, and/or GLP and scientifically relevant);
- generally, primary emphasis shall be placed upon *existing human experience* and data, followed by animal experience and testing data, followed by other sources of information. However evaluation of available gathered information must be performed on a case-by-case basis and with *expert judgement*;
- *conflict between humans and animals findings* shall be solved evaluating the quality and reliability of the evidence from both sources;
- moreover attention should also be paid to *information contained in the internet as it can be highly volatile.* According to the Article 49 of the CLP Regulation the gathered information must be adequately kept possibly with the search strategy.

Finally the problem of lack of data remains the key problem (*e.g.* specific aquatic toxicity data are lacking for many substances; chronic toxicity data are lacking for some substances in the NLM online databases; for several substances, essentially not relevant information are located in available open sources).

Data gap on available information on the chemical hazards has been well document in the last decades. Several studies performed by European Commission and US EPA equally have demonstrated that basic chemical data, even for high priority volume chemicals (HPVC) is only minimally available, stimulating different initiatives and policies [11]. When data are lacking CLP classifications can be developed by read-across and weight of evidence strategies but a prominent contribution is expected under REACH regulation as additional information on (hazardous) properties of existing substances will come directly from data contained in registrations, from which a progressive relevant improvement could be obtained in available information.

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Conflict of interest statement

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Classification & Labelling Inventory: role of ECHA and notification requirements

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Summary. The CLP Regulation introduces the criteria of the UN Globally Harmonised System of Classification and Labelling (UN GHS) in the EU. The European Chemicals Agency (ECHA) manages the CLP related tasks – such as harmonised classification and labelling, handling requests for alternative names and maintaining the Classification & Labelling Inventory (C&L) – to ensure consistent implementation in the EU. The obligations for industry depend on their role in the supply chain. Manufacturers and importers have to notify to ECHA the identity and classification and labelling of substances within one month of placing them on the market either on their own or in a mixture, and regardless of the quantitity. As of 3 January 2011 ECHA has received some 3.1 million notifications of over 107 000 substances. This information is stored in the C&L Inventory and accessible to Member State Competent Authorities. The non-confidential information will be made publicly available on ECHA's website in 2011.

Key words: Regulation (EC) no. 1272/2008, CLP, C&L notification, C&L Inventory, ECHA, harmonised C&L.

Riassunto *(Inventario delle classificazioni e delle etichettature: ruolo dell'ECHA e requisiti della notifica)*. Il Regolamento CLP introduce nell'Unione Europea i criteri del sistema armonizzato globale delle Nazioni Unite per la classificazione ed etichettatura. L'European Chemicals Agency (ECHA) gestisce le attività relative a tale regolamento – quali la classificazione ed etichettatura armonizzate, le richieste di nomi alternativi e l'inventario delle classificazioni e delle etichettature – per garantire una implementazione coerente nell'Unione Europea. Gli obblighi per le industrie dipendono dal loro ruolo nella catena d'approvvigionamento. Fabbricanti e importatori devono notificare all'ECHA l'identitá e la classificazione ed etichettatura delle sostanze, sia in quanto tali sia contenute in una miscela, entro un mese dalla loro immissione sul mercato, e indipendentemente dalla quantità. Al 3 gennaio 2011 l'ECHA ha ricevuto circa 3,1 milioni di notifiche per oltre 107 000 sostanze. Questa informazione è contenuta nell'inventario delle classificazioni e delle etichettature ed è accessibile alle autorità competenti degli stati membri. Le informazioni non-confidenziali saranno rese pubbliche sul sito di ECHA nel 2011.

Parole chiave: Regolamento (CE) no. 1272/2008, CLP, notifica, Inventario C&L, ECHA, classificazione ed etichettatura armonizzata.

INTRODUCTION

Trade in chemical substances and mixtures is global and the hazard communication between regulatory areas has been complex due to different classification and labelling systems. The United Nations has developed over 12 years harmonised criteria for classification and labelling of chemicals together with general principles of their application, the so called Globally Harmonised System of Classification and Labelling of Chemicals (GHS). The new system will facilitate worldwide trade in chemicals while protecting human health and the environment [1].

The Regulation (EC) no. 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP Regulation) introduces the GHS criteria in the EU. CLP has entered into force on 20 January 2009 and until 1 June 2015 it will stepwise replace the previous legislation for chemical substances and preparations [2].

THE EUROPEAN CHEMICALS AGENCY (ECHA)

ECHA was founded in 2007 and placed in Helsinki, Finland, as one of the agencies of the European Union. It manages the EU chemicals Regulation (REACH) [3] and the new Regulation on classification, labelling and packaging of chemicals (CLP) across Europe. In particular the REACH Regulation has been designed to completely overhaul the way that the safety of chemicals is assessed, implemented and communicated within Europe. REACH lays down the duties of the Agency.

Structure of the Agency

The day to day management of the Agency is the responsibility of the executive director.

The Governing body of the Agency is the Management Board which is made up of representa-

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tives from each of the EU and EEA Member States and representatives of the European Commission, the European Parliament and independent persons nominated by the Commission. In addition to the Management Board there are three different scientific committees – the Committee for Risk Assessment (RAC), the Committee for Socio-Economic Analysis (SEAC), and the Member State Committee (MSC) – the Forum for Exchange of Information on Enforcement, and the Board of Appeal. The Committee for Risk Assessment provides the best possible scientific advice on the risks of chemicals. One of its tasks is to provide opinions on proposals for harmonisation of classification and labelling.

OVERVIEW ON OBLIGATIONS UNDER CLP

ECHA's role

ECHA manages the process for harmonisation of classification and labelling (C&L), it maintains the C&L Inventory, and assesses requests for the use of an alternative name for a substance in a mixture, if this mixture is classified, labelled and packaged according to the CLP criteria. ECHA also provides guidance and IT-tools for industry to comply with the requirements of the CLP Regulation.

Industry's obligation

Companies' obligations and responsibilities under CLP depend on their role in the supply chain. CLP affects everybody who is:

- a registrant under REACH;
- a manufacturer or importer of substances or mixtures (preparations) that he places on the market;
- a downstream user, who uses substances or mixtures supplied to him for the formulation of other products that he places on the market, *e.g.* adhesives, cleaning products, paints, motor oils;
- a distributor (retailer), who stores and places on the market a substance or a mixture for others;
- a producer or importer of articles that are explosive or that contain substances that are intentionally released or are on the candidate list of substances of very high concern;
- involved in research and development of chemicals.

Each of these roles implies specific obligations under CLP and it is worth to note that a company may have several roles.

Manufacturers, importers and downstream users, incl. formulators of mixtures and re-importers, are responsible for classifying, labelling and packaging their substances and mixtures before placing them on the market. CLP also requires manufacturers and importers to classify substances subject to registration or notification under REACH, even if they are not placed on the market. If a substance has a harmonised classification in the EU, it has to be used. Substances with harmonised classification are listed in Annex VI to CLP. Additionally, the "non-harmonised" hazard classes have to be self-classified if the classification criteria are met, based on adequate and reliable information.

Distributors (including retailers) have to label and package substances and mixtures in accordance with the classification.

Table 1 | *Scope of the notification: specific substances and roles in the supply chain [4, 13]*

Re-fillers need to notify only if they receive substances and mixtures from an actor outside the EU.
Re-importers do not need to notify if they fulfil all the criteria to be considered as downstream users.
Distributors (incl. retailers) need to notify only if they import substances and mixtures from a non-EU source, as they count as importers in these cases.
Recovered substances have to be notified. During notification (via REACH-IT), it is possible to agree by means of a mouse-click to the C&L information of the original substance as provided by the registrant in the Inventory.
"NONS" under the Dangerous Substance Directive are deemed to be registered under the REACH. Dossiers have to be updated with the CLP classifications without undue delay after 1 December 2010 according to REACH. Other manufacturers and importers need to notify in the Inventory. For NONS notified below 1 tonne under Directive 67/548/EEC and for which no tonnage band update has been done, a separate notification to the Inventory will have to be made if the substance is classified as hazardous and placed on the market.
Waste under the Waste Framework Directive is exempted from CLP. Instead, residues recovered as substances or mixtures do fall under the scope of CLP.
Ingredients of substances or mixtures that in the finished state are exempted from CLP (*e.g.* cosmetic and medicinal products) have to be notified if placed on the market.
Food and feeding stuffs are normally exempted from CLP.
A polymer is a substance and must be notified if it fulfils the criteria for classification as hazardous and it is placed on the market. By contrast, **monomers** contained in such polymers are not considered as being placed on the market, and their notification is not necessary.
Alloys are considered special preparations (CLP terminology: mixtures) under the REACH and CLP Regulations. The components of alloys need to be notified to the Inventory in case they are hazardous and contained in the alloy above specified concentration limits
Substances for scientific research and development (R&D) and **Substances for product and process orientated research and development** (PPORD) should be notified to the C&L Inventory, irrespective of the tonnage, where they meet the criteria for classification as hazardous and when they are placed on the market.
The classification and labelling of **active substances contained in plant protection products (PPPs) and biocidal products (BPs)** is normally harmonised for all hazard classes and appears both in Tables 3.1 and 3.2 of Annex VI to the CLP Regulation. Notification to the Inventory must always be done for active substances when they are placed on the market.

Manufacturers and importers further have the obligation to notify to ECHA certain information on the substances that they are placing on the market. This information is stored in the Classification & Labelling Inventory. Re-fillers and distributors only need to notify if they import their chemicals from a non-EU country *(see also Table 1)*.

NOTIFICATION TO THE C&L INVENTORY

Obligation to notify

Manufacturers and importers of hazardous substances have to notify the C&L of their substances to ECHA within one month after placing them on the EU market, unless the substance is exempted from CLP. This applies to hazardous substances on their own or in mixtures above concentration limits leading to the classification of the mixture. For hazardous substances there is no tonnage threshold for notification. Another group of substances that need to be notified are those that are subject to registration under REACH. This means that also non-classified substances that are manufactured in quantities of more than 1 tpa need to be notified where they are placed on the EU market.

However, the duty to notify does not apply if the manufacturers or importer has already submitted the corresponding information as part of a registration under REACH. In that case, the information needed for the C&L Inventory will be extracted from the registration dossier.

A C&L notification can also be made by a group of manufacturers or importers.

Table 1 gives some examples for substances categories and ECHA's interpretation whether they fall under the scope of CLP. They are based on the frequently asked questions (FAQ) and the question and answers (Q&A) sections published on the ECHA website, which should be consulted for more detailed explanation [4, 5].

The first deadline for notification was 3 January 2011 and applied to all substances that were on the market on 1 December 2010. For substances placed on the market later EU[1] based manufacturers and importers have to notify the respective classification and labelling within one month of placing them on the market.

Placing a chemical substance or mixture on the market means making it physically available to third parties, regardless of whether this is in return for payment or free of charge. Substances which are either imported or sent as samples are also considered as being placed on the market. A substance is regarded as imported as soon as it is physically brought into the Communities customs territory.

A non-EU company can appoint one of its importers to notify on behalf of all the others. Where an only representative has already registered a substance before it has to be notified, the importers covered by the registration do not need to notify to the Inventory.

Content of the notification and choice of tools

Before submitting the C&L notification the manufacturer or importer placing a substance on the market needs to make sure that the C&L of the substance is correct. This means that he has to gather all available and relevant information and examine the information to ensure its adequacy and reliability. The next step is the evaluation of the available information against the classification criteria and the decision on the C&L. Detailed guidance on how to apply the criteria is available on the ECHA website [6, 7].

The notification to ECHA must include the following information:

- the identity of the notifier, as specified in Annex VI of REACH;
- the identity of the substance, as specified in Annex VI of REACH;
- the classification of the substance according to the CLP criteria;
- where the substance has been classified in some but not all CLP hazard classes or differentiations, an indication of whether this is due to lack of data, inconclusive data, or data which are conclusive although insufficient for classification;
- where applicable, specific concentration limits, or M-factors related to the classification as hazardous for the aquatic environment, *i.e.* acute category 1 and chronic category 1, together with a justification for their use; and
- the labelling elements for the substance, including the supplemental hazard statements referred to in CLP Article 25(1).

Submission of a notification is done via the REACH-IT portal on the ECHA website. First, the company has to sign up in REACH-IT and create an account. Companies can submit only one notification per substance.

Companies can notify their substances either individually or as a group of manufacturers or importers. When notifying as a group, only one notification is submitted on behalf of all the members of the group.

To carry out the notification, three tools are available on ECHA's website: IUCLID 5, a bulk notification tool, and an online tool.

In IUCLID 5, a dossier is created using a *CLP notification* template. IUCLID 5 is the only tool that allows the specification of more than one composition and more than one classification and labelling for the same substance. The tool is useful for companies which need to submit their REACH registration dossiers after the January 2011 notification deadline because in this way, the information used for making a notification will already exist in IUCLID for the upcoming registration.

The bulk notification tool is based on XML format and allows to submit notification information for several substances in a single file. An additional excel tool is made available to make the creation of the XML file easier. The bulk notification tool can also be used

[1] *The reference to the EU in this text also includes Iceland, Norway and Liechtenstein.*

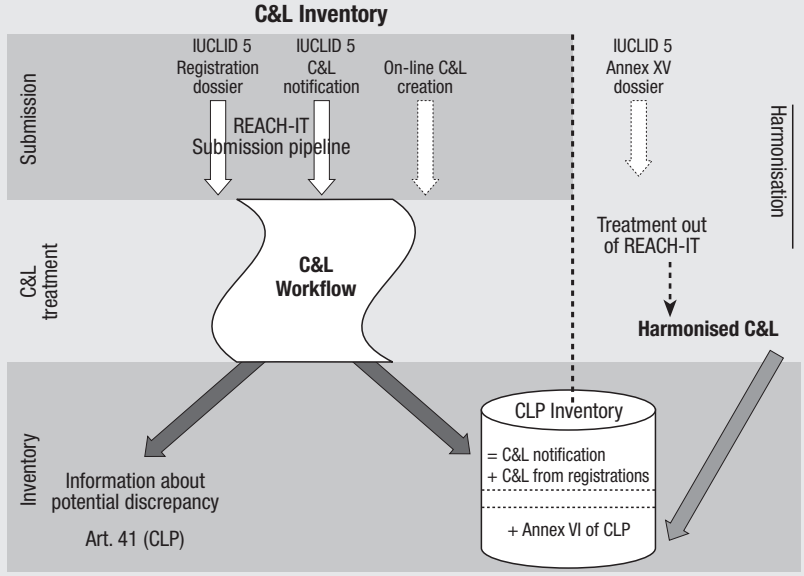

Fig. 1 | *Information flow in the C&L Inventory (Source: ECHA).*

for non-classified substances. However, the prerequisite is that the substances have either an EC or CAS number and they have only one composition or one classification and labelling.

With the online tool the required information is manually entered directly into REACH-IT. This might be the preferred option if a company is only notifying a few substances. The tool has an Agree button which allows the notifier to agree with an existing entry in the Inventory for the same substance while creating his own notification.

All of the tools are compatible with each other and notifications made with one can be updated with the others. On top of this, all the tools can be combined with a submission on behalf of a group [8]. User manuals are available on ECHA's website in 22 languages [9-13].

The CLP Regulation requires that in case the notification results in an entry on the Inventory which differs from another entry for the same substance, the other notifiers and/or registrants shall make every effort to come to an agreed entry to be included in the Inventory (CLP Article 41). However, a substance may be classified differently to another entry, provided the reasons are included in the notification.

In contrast, where the substance has a harmonised classification, the notifier shall classify in accordance with the harmonised classification listed in Part 3 of Annex VI to CLP and include this classification in the notification.

Please note that where an M-factor is not given in Part 3 of Annex VI for substances classified as hazardous for the aquatic environment (category acute 1 or chronic 1) the notifier shall set an M-factor for the substance, based on available data [6].

The C&L Inventory

The C&L Inventory is a central database of basic C&L information of substances on the EU market irrespective of their production volume. It collects the C&L information of substances submitted to ECHA in the REACH registration dossiers and C&L notifications under CLP. It also includes the list of substances having a harmonised C&L, *i.e.* listed in Annex VI of CLP. The full database is accessible to the Member State Competent Authorities. Key information of the database will be extracted to the public Inventory which will be available at the ECHA web site in 2011. Companies' identity or confidential information will not be dis-

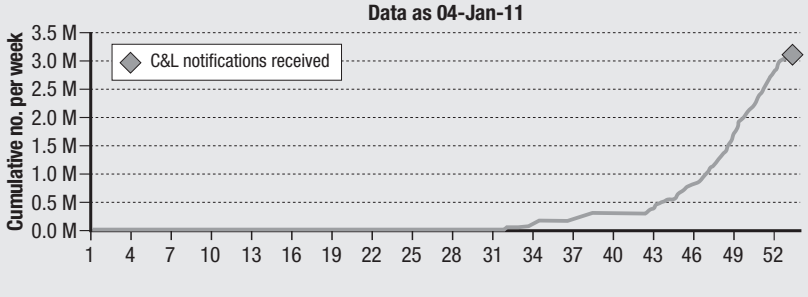

Fig. 2 | *Trends in C&L notifications received in 2010-2011 by week. (Source: ECHA).*

Table 2 | *C&L notifications per country – TOP 10 [14]*

Country	Percentage of notifications received (total no. 3.1 million)
Germany	26%
United Kingdom	16%
France	9%
Belgium	6%
Italy	6%
Spain	4%
Poland	4%
The Netherlands	4%
Hungary	3%
Czech Republic	3%

closed. *Figure 1* gives an overview of the information flow in the C&L Inventory.

FIRST EXPERIENCE FROM C&L NOTIFICATIONS BY THE 3 JANUARY 2011 DEADLINE

Some companies have notified their substances already at the beginning of 2010 but the peak of C&L notifications was received in December 2010 *(Figure 2)*. Submissions from Germany, the United Kingdom and France together account for about half of the notifications. *Table 2* lists the notifications received per country for the "Top 10". By the deadline of 3 January 2011 more than 3.1 million notifications covering a total of over 107 000 substances were received by ECHA. The submitted notifications enable ECHA to establish the C&L Inventory.

ECHA will analyse the Inventory and improve the guidance provided to notifiers as necessary. Based on the first checks it seems that some notifiers might have had problems in correctly applying the harmonised classification and labelling that are based on the so-called group entries. Group entries in Annex VI of CLP cover more than one substance, for example "arsenic compounds, with the exception of those specified elsewhere in Annex VI". In some cases substances may even be covered by more than one group entry. Lead oxalate (EINECS no. 212-413-5) is for instance covered by the entry for lead compounds (Index no. 082-001-00-6) as well as for salts of oxalic acid (607-007-00-3) (Foreword to Annex I of Dir. 67/548/EEC; General explanatory Notes; Groups of substances) [15]. In these cases, the labelling of the substance reflects the labelling for each of the two group entries. In cases where different classifications for the same hazard are given, the most severe classification shall be applied [2]. The following explanations are provided in the legislation:

CLP Annex VI Part I: Introduction to the list of harmonised classification and labelling
1.1.1.5 Entries for groups of substances.
"A number of group entries are included in Part 3. In these cases, the classification and labelling requirements will apply to all substances covered by the description.
In some cases, there are classification and labelling requirements for specific substances that would be covered by the group entry. In such cases a specific entry is included in Part 3 for the substance and the group entry will be annotated with the phrase 'except those specified elsewhere in this Annex'.
In some cases, individual substances may be covered by more than one group entry. In these cases, the labelling of the substance reflects the labelling for each of the two group entries. In cases where different classifications for the same hazard are given, the most severe classification shall be applied.
Entries in Part 3 for salts (under any denomination) cover both anhydrous and hydrous forms unless specifically specified otherwise.
EC or CAS numbers are not usually included for entries which comprise more than four individual substances".

The fact that group entries often do not have an allocated EC or CAS number might be one of the reasons that some notifiers fail to notice that the harmonised classification and labelling need to be applied to their substance.

The receipt of classification and labelling notifications under the CLP Regulation is an ongoing process. Manufacturers and importers placing on the market a hazardous substance on its own or in a mixture, or a substance subject to REACH registration, shall notify its classification and labelling within one month to ECHA. Therefore, the number of notified substances and notifications received will continue to increase and the C&L Inventory will be updated regularly.

CONCLUSION

With the C&L Inventory the EU implementation of GHS contains a strong element of hazard documentation and communication for all substances placed on the market irrespective of their production volume. The first submission deadline posing a challenge for ECHA and industry alike has been successfully passed. The number of notifications received indicates that manufacturers and importers make an effort to fulfil their obligations. A first spot check of the Inventory however shows that in some cases the quality needs to be improved, especially when applying harmonised classification for group entries. Any such observations made in the notifications received will be used to provide better guidance to industry and thereby ultimately improving the quality of C&L notifications and the Inventory as a whole.

This text reflects the personal view of the author and does not necessarily constitute the official position of ECHA.

Conflict of interest statement

There are no potential conflicts of interest or any financial or personal relationships with other people or organizations that could inappropriately bias conduct and findings of this study.

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CLP application to nanomaterials: a specific aspect

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Summary. This paper aims at describing some relevant aspects related to the classification, labelling and packaging of nanomaterials. Concerns have been raised about potential adverse effects to humans or the environment as result of impacts of nanomaterials. The new Regulation (EC) no. 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP) does not contain any specific definition or provision related to nanomaterials nevertheless they are covered by the definition of substance set in the Regulation. It is recognized that different particle sizes or forms of the same substance can have different classification. Thus, if substances are placed on the market both at nanoscale and as bulk, a separate classification and labelling may be required if the available data on the intrinsic properties indicate a difference in hazard class between the two forms. CLP Regulation requires the manufacturer or importer to ensure that the information used to classify relates to the forms or physical states in which the substance is placed on the market and in which it can reasonably be expected to be used. Moreover, CLP demands testing relating to physical hazards to be performed if such information is missing or not adequate to conclude on classification. Further developments of the CLP guidance documents and implementation tools are needed in order to cover nanomaterials more specifically.

Key words: nanomaterial, classification, labelling, substance.

Riassunto *(Applicazione del regolamento CLP ai nanomateriali: aspetti specifici)*. Lo scopo di questo lavoro è descrivere gli aspetti rilevanti connessi alla classificazione, all'etichettatura e all'imballaggio dei nanomateriali. L'impatto dei nanomateriali ha suscitato preoccupazioni legate agli effetti potenzialmente negativi per la salute umana e per l'ambiente. Il nuovo Regolamento CE 1272/2008 sulla classificazione, etichettatura e imballaggio di sostanze e miscele (CLP) non contiene definizioni specifiche o provvedimenti espliciti sui nanomateriali, tuttavia essi ricadono nella definizione di sostanza prevista dal Regolamento. È stabilito che forme e dimensioni diverse di una stessa sostanza possano avere classificazioni differenti. Per le sostanze immesse sul mercato sia in nanoscala che in forma *bulk* sono richieste classificazione ed etichettatura diversificate quando i dati disponibili sulle proprietà intrinseche indicano che esistono differenze nelle classe di pericolo. Il Regolamento CLP impone al fabbricante o all'importatore di assicurare che le informazioni usate per la classificazione si riferiscano allo stato fisico e alla forma con i quali la sostanza è immessa sul mercato ed è ragionevole aspettarsi venga utilizzata. Inoltre, il CLP richiede che vengano effettuati i test relativi al pericolo fisico qualora le informazioni indispensabili per la classificazione risultino inadeguate o mancanti. Successivi sviluppi di guide tecniche e strumenti utili per l'implementazione del CLP sono necessari per garantire ai nanomateriali un quadro legislativo sempre più specifico.

Parole chiave: nanomateriale, classificazione, etichettatura, sostanza.

INTRODUCTION

The new classification, labelling and packaging (CLP) Regulation [1] provides the general framework for the classification, labelling and packaging of chemicals implementing the Globally Harmonised System of Classification and Labelling of Chemicals (GHS) [2]. Nanomaterials are not mentioned in the GHS mainly because knowledge is lacking on the relevance of available test methods for nanomaterials and whenever there is any reason to believe new test methods are required very little is known about how these methods should be designed [3].

In the light of the complexity of nanosciences and nanotechnologies [4, 5] and the wide variety of potential applications, a very broad approach is needed. The possible scientific and economic potential is definitely considered extremely high [6].

Different kinds of nanomaterials have a widespread use in common household items, from sports gear and sunscreens to socks and dresses, from beds and detergents to mobile phones and electronic devices. The characteristics of materials, particularly their colour, strength, conductivity and reactivity, change substantially when their atoms and mol-

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ecules are manipulated. Innovation can bring benefits, but possible risks too. Most nanomaterials are probably perfectly safe for the general public, particularly in solid form, but there is some uncertainty about health risks if, for instance, toxic nanoparticles enter the body through the skin or are inhaled [7], and about environmental risks when nanoparticles are released into soil and water systems.

At present, the debates underway in the European countries and public and private institutions responsible for managing health and environmental risks recognise on one hand the advantages of nanothecnology based innovations and on the other hand the lack of knowledge on risks related to exposure of humans and environment to nanomaterials.

Due to the limited information and resources the regulators are now facing the challenge of adapting an old regulatory framework to a rapidly changing technology.

One of the most recent work on regulatory aspects of nanomaterials in REACH (registration, evaluation, authorization and restriction of chemicals) [8], is being carried out in the framework of Competent Authorities subgroup on nanomaterials, where issues such as substance identification of nanomaterials, information requirements on intrinsic properties (including testing strategies), exposure assessment (including exposure scenarios, evaluation of risk management and mitigation measures and exposure estimation), as well as hazard and risk characterization for chemicals safety assessment are being discussed among Europe Member States experts, industries, NGOs (non-governmental organizations) and Commission representatives. The outcomes of these debates serve as basis for discussions for CARACAL (Competent Authorities for REACH and CLP) where policy decisions on REACH and CLP implementation are being made. A further outcome of those discussions will be the development of guidance documents and implementation tools designed to cover nanomaterials more specifically.

BACKGROUND

What is a nanomaterial and what changes occur at nanoscale

Nanomaterials have extremely small size as their defining characteristic, although there is not yet an agreed international definition for the term "nanomaterial".

Nanomaterials are understood to be either so-called "nano-objects" or "nanostructured materials" according to the UNI CEN ISO/TS 27687:2010 [9].

The current mostly used working definition of nanomaterials is "a material having at least one dimension equal to 100 nanometres or less". To put nanomaterials into perspective, up to 10 000 could fit across a human hair. Nanomaterials can be at nanoscale in one dimension (*e.g.* surface films), two dimensions (*e.g.* strands or fibres), or three dimensions (*e.g.* particles). They can exist in single, fused, aggregated or agglomerated forms with spherical, tubular, and irregular shapes. Common types of nanomaterials include nanotubes, dendrimers, quantum dots and fullerenes.

The 100 nm size boundary used in these definitions, however, only loosely refers to the nanoscale around which the properties of materials are likely to change significantly from conventional equivalents.

Nanomaterials having specific properties may require a different classification compared to the bulk material, also when the nanoform is derived from a bulk substance.

How can a nanomaterial be produced? The manipulation of matter at the nanoscale, can employ either a *top-down* or a *bottom-up* technique. Most nanomaterial manufacturing processes are top-down, which means the material is produced in large primary particles and broken into smaller pieces by grinding or down-cut milling. Depending on the process and the applied forces the final content of particles at nanosize can vary. Any top-down process is likely to result in a certain fraction of nano-objects and their aggregates and agglomerates and it could include a portion of not intentionally produced by-product at nanoscale. On the other hand, bottom-up nanomaterial manufacturing processes are those in which atoms are intentionally controlled during the manufacturing operation to result in nano-objects and their aggregates and/or agglomerates. Both top-down and bottom-up approaches produce materials designed at the nanoscale level to take advantage of their small size and innovative properties which are commonly not identified in their bulk counterparts. Knowledge of the manufacturing process can help to identify and characterize the derived nanomaterial.

The two crucial causes why materials at the nanoscale can display dissimilar characteristics are the resulting amplified specific surface area and new quantum effects. Nanomaterials have a much greater surface area to volume ratio than their bulk forms, which can lead to greater chemical reactivity and influence their strength. Also at the nanoscale, quantum effects can become much more important in regulating the materials properties and characteristics, leading to novel optical, electrical and magnetic behaviors.

The same properties that distinguish nanomaterials may cause possibly human health and environmental hazards. By way of example, the increased surface reactivity is a desired property for many intended applications of nanomaterials, such as catalysts, however, this characteristic can lead to a greater toxicity for cells and living organisms. The physicochemical properties of nanomaterials are determined by the chemical composition, surface structure, small size and associated increase in surface to volume ratio, solubility, shape and aggregation. The influences of physicochemical properties on the toxicological and eco-toxicological profile of nanomaterials are not yet fully understood. Changes

in physicochemical properties can also increase the potential for some nanomaterials to exhibit fire, explosion hazards or catalytic activity. Limited data from preliminary studies in vertebrates have shown that some nanomaterials can accumulate in the lungs and translocate to the blood, cross the blood-brain barrier and produce inflammatory responses [10]. Moreover, direct interaction of nanoparticles with nucleic acids have been shown by *in vitro* studies. Parallels have also been drawn with the incidentally produced nanoparticles (such as combustion products) and their associated adverse effects on human health. Nevertheless, to date there are no confirmed reports on adverse effects to humans or the environment as a result of exposure to engineered nanomaterials.

Nanomaterials definition in the regulatory context

According to REACH and CLP Regulations, substance means a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition. REACH and CLP deal with substances, in whatever size, shape or physical state. Therefore this definition includes all physical states, crystal structures, and dimensions of particles of the substance in powder form or in suspension, even if the particle size would go beyond the nanoscale to individual atoms or molecules. ECHA stated on 3 December 2007 at the European NanOSH Conference in Helsinki that REACH treats both the bulk material and the nano-sized material, as the same substance. The Agency added that this, however, does not prevent who is responsible of placing on the market of a chemical from identifying its dangerous properties depending on its size and classify the different types accordingly.

A definition is required in order to provide increased clarity and consistency with respect to the term nanomaterial for use in Regulations laying down provisions on substance. As REACH and CLP are both based on the substance concept, it will be essential for their application to nanomaterials to set up a working definition of the term nanomaterial.

In order to assemble a science-based definition of nanomaterials, the services of the European Commission need clarification on size ranges, physical-chemical properties, relevant thresholds and most appropriate metrics to express such thresholds. The recent draft Recommendation on the definition of the term nanomaterial is based on the work done by the Commission's Joint Research Centre and the input of the Scientific Committee for Emerging or Newly Identified Health Risks (SCENIHR) [11].

The aim of the recommendation is to determine when a material should be considered as a nanomaterial, in particular for legislative and policy purposes in Europe. It should cover all nanomaterials, whether they are of natural, incidental or manufactured origin. In the current draft definition the three following criteria are considered. A material can be considered a nanomaterial if meets at least on of these criteria:

- consists of particles, with one or more external dimensions in the size range 1 nm - 100 nm for more than 1% of their number size distribution;
- has internal or surface structures in one or more dimensions in the size range 1 nm– 100 nm;
- has a specific surface area by volume greater than 60 m^2/cm^3, excluding materials consisting of particles with a size lower than 1 nm.

The draft recommendation came through the public consultation phase and is now under revision in light of the received comments.

CLASSIFICATION AND LABELLING OF NANOMATERIALS

General obligations

According to CLP Regulation, who is responsible of placing on the market of substances and mixtures are obliged to label and package them. Moreover, hazardous substances have to be notified to ECHA, with the purpose of establishing a CLP Inventory which will make the information specified in REACH Article 119(1) and (2) publicly available. According to REACH transitional provisions related to tonnage band and hazard of manufactured or imported substances, a registration dossier must be submitted to ECHA, which includes a classification and labelling section. Independent of volume of manufacture or import, the notifications to the CLP Inventory will provide ECHA with information on hazardous substances and their forms, including nanomaterials, on the market. The information gathered through the CLP Inventory has to be assessed carefully together with other relevant information on nanomaterials, especially related to the definition of nanomaterial, on-going discussion on substance identity of some nanomaterials and information on nanomaterial properties.

The classification and labelling of nanomaterials should follow the rules set out in CLP. It is worth recalling that CLP Article 9(5) states "When evaluating the available information for the purpose of classification, the manufacturers, importers and downstream users shall consider the forms or physical states in which the substance or mixture is placed on the market and in which it can reasonably be expected to be used". That is why, the hazard classification should be based on available data that relate to the intrinsic properties of the substance or mixture placed on the market (CLP Article 5(1), 6(1) and 8(6)). Manufacturers, importers and downstream users shall take all reasonable steps available to them to make themselves aware of new scientific or technical information that may affect the classification of the substances or mixtures they place

on the market. When a manufacturer, importer or downstream user becomes aware of such information which he considers to be adequate and reliable, he shall without undue delay carry out a new evaluation and conduct additional testing accordingly.

Ultimately, information on classification and labelling of substances and mixtures as well as instructions for a safe handling have to be communicated to the supply chain via a Safety Data Sheet (SDS). Since many engineered nanomaterials are not currently classifiable as hazardous, it will be no mandatory to prepare an SDS or include information on label. Anyway, SDS should reflect current state of knowledge on chemical safety thus it is extremely important to update it as soon as new information about hazard profile of a nanomaterial is being generated.

Testing nanomaterials for classification purpose

Substances may exist in different forms due to changes in properties such as crystal structure, particle size, homogeneity and viscosity. Other than form, physical state may change depending on agglomeration state, surface treatment, moisture content, residual solvent, activation or stabilisation. It is important to test a sample for classification purpose which is representative for the substance or mixture as it is placed on the market and being aware of changes in its form or physical state carry out evaluation to identify any effects on the classification. If nanomaterials are manufactured/imported both at nanoscale and as bulk a separate classification and labelling may be required if the intrinsic properties at nanoscale lead to a different classification from the one at the bulk. Nickel and nickel powder (particle diameter < 1 mm) is a good example of how a substance with different particle sizes or forms can have different classifications.

The lack of knowledge on the peculiarities of the new nanotechnology applications, in terms of the substance identification and hazard profile, makes very difficult to establish standardized and appropriate criteria in order to evaluate the toxicological properties of nanomaterials (SCENIHR 2006 [12] and 2007 [13]). The Organisation for Economic Co-operation and Development (OECD) and the International Organization for Standardization (ISO) recognise the need for the physical-chemical properties of nanoparticles to be aimed at risk assessment of nanomaterials. The principal physical specifications concerning nanoparticle evaluation are: the size, shape, specific surface area, aspect ratio, agglomeration/aggregation state, size distribution, surface morphology/topography, structure including crystallinity and defect structure and solubility. The most important chemical specifications are: structural formula/molecular formula, composition (including degree of purity, known impurities or additives), phase identity, surface chemistry, charge tension, reactive sites, physical structure, photocatalytic properties, zeta potential and hydrophilicity/lipophilicity (SCENIHR, 2009 [4]).

Furthermore, the SCENIHR affirmed that a general rule does not exist regarding the hazard enhancement of a substance when scaling down in size. Thus the hazard characterisation of nanoforms should be achieved with the case by-case approach.

Another important issue, which has been raised and is already under discussion within the OECD Working Party on Manufactured Nanomaterials (WPMN), is the adequacy of current test guidelines to deliver results for hazard classification of nanomaterials. To date the conclusion is that "Many of the OECD Test Guidelines are applicable, with conditions in some cases, while some are inadequate for testing nanomaterials as measuring, dosing, delivery and tracking nanomaterials are not reliably accomplished at this stage Therefore, the review of OECD Test Guidelines reinforced the need for a guidance document(s) for sample preparation and dosimetry". Accordingly, the modified test guidelines can be used to provide information for the hazard assessment.

With regards to nanomaterials, due to the impact of the increased surface area on physicochemical properties, if information only exists for bulk materials it should be assessed if this information is also applicable to nanomaterials. Information derived when fulfilling the registration requirements in REACH, according to the test methods Regulation (440/2008/EC) [14], will not be sufficient to determine all physical hazards in accordance with CLP. Any evaluation of particulates in the context of CLP Regulation should be conducted in accordance with the principle of using the worst case scenario where the finest relevant fraction of the form and physical states as placed on the market, should be used when testing for physicochemical hazards.

The accordance with the test method Regulation [14] applying the OECD test guidelines and with the Regulation on the good laboratory practice (GLP) is essential for the hazard assessment of substances. Taking into account the evolving situation in testing methods and guidelines as well as scientific opinions from the EU Scientific Committees, the preliminary review of the OECD-WPMN concluded that current test guidelines for human health endpoints, together with the preliminary guidance notes on sample preparation and dosimetry, are considered applicable for nanomaterials. However, additional consideration needs to be given to the physicochemical characteristics of the material tested, including such characteristics in the actual dosing solution. In some cases there will be a need for further modification to the OECD guidelines. This applies particularly to studies using the inhalation route and to toxicokinetics (ADME) studies. There are, however, difficulties with regard to test guidelines for environmental endpoints.

Classification and labelling section of REACH registration dossier

When nanoforms of a known and already registered substance in bulk are commercialized, the registration dossier required by REACH Regulation has to be updated including different classification and labelling of the nanoform [15].

Registrants as intended by REACH Regulation are envisaged to use the following approaches in the classification and labelling of nanomaterials:

- the data sharing within the substance information exchange forum (SIEF) should cover all relevant information including at least sizes, forms and morphologies;
- to determine whether changes in the substance form influence considerably the hazardous properties;
- to evaluate all available information on nanomaterials in the hazard assessment;
- to pay special attention to the appropriateness of the sample preparation and dosimetry used in the testing of nanomaterials;
- classification should be done on a case-by-case basis;
- on the basis of the classification in accordance with CLP, nanomaterials should also be labelled and packaged accordingly.

When approaching a registration dossier the first issue to be solved in case of a nanomaterial appears to be the substance identification. The *Guidance for identification and naming of substances under REACH* [16] recognises that some substances which can be identified by their chemical composition need to be further specified by additional identifiers to get their own substance identification. To give an example, nanomaterials are often surface treated. In fact, surface modifications are relevant for their identification. A physical bonding (*e.g.* van der Waals links) between the nanoparticle and the surface treating agent could be considered as a mixture of two substances. In this case, the two substances would be registered on their own. A chemical bonding instead could be considered as another substance than the untreated particle.

For the identification of nanomaterials two approaches are discussed: one approach is to consider nanomaterials as "substances of defined chemical composition and other main identifiers". There is consensus that the key identifier/characteriser for nanomaterials is the size. Other potential identifiers/characteriser, *e.g.* surface area or optical activity, are linked to size. Primary particle size (and size distribution) and aspect ratio were considered as most important additional identifiers/characterisers. Nature and properties of coating/functional groups/surface chemistry could be an additional identifier/characteriser, (binding) forces/energy between nanoparticle and coating or functional group should be considered. Furthermore, stability/agglomeration/aggregation could be taken into account for the identification/characterisation of nanomaterials. The other approach is to consider nanomaterials as UVCB substances (substances of unknown or variable composition, complex reaction products or biological materials) due to the variability of the additional identifiers, *e.g.* size, chemical composition and surface treatment. Grouping nanomaterials of different size as a UVCB substance could follow the approach for "substances with variations in carbon chain length". The UVCB approach was considered to be more flexible allowing capturing the variability of identifiers values.

IUCLID (International Uniform Chemical Information Database) is a software application to store and exchange data on intrinsic and hazard properties of chemical substances within REACH and CLP context. In particular, the preparation of a IUCLID dossier for nanomaterials is in principle no different from the preparation of a dossier for any other substance with the exception that internationally agreed naming and identification conventions are not yet available for nanomaterials. This can potentially create issues with consistency in the identification information included in the dossier. For cases where the registrant has concluded that the nanomaterial is a nanoform of a substance, it is suggested to include information on the nanoform in the dossier analogously to any other composition of a substance.

There are two new fields in IUCLID version 5.2 [17] which enables the information "nanomaterial" to be included in the dossier. This version has been used for the first REACH registration phase and

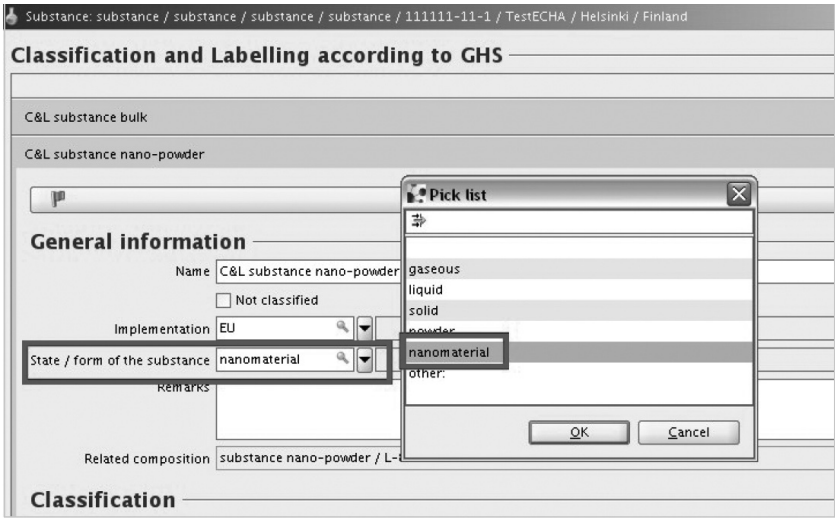

Fig. 1 | *Section 2.1 of the International Uniform Chemical Information Database (IUCLID) dossier in which the form of the substance picklist includes "nanomaterial" [17].*

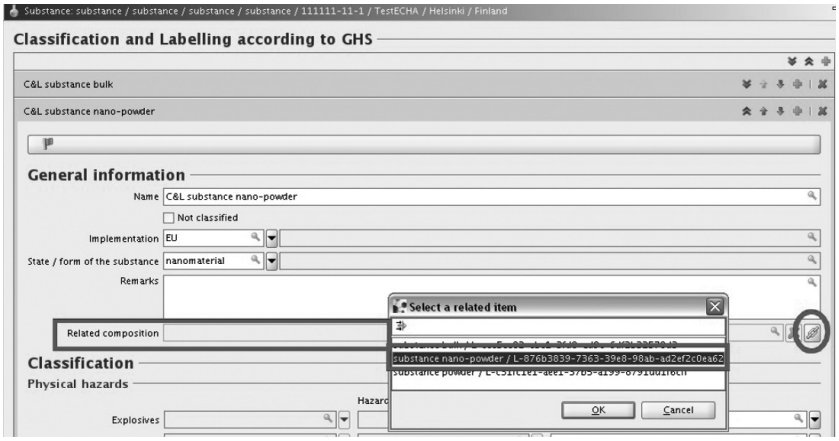

Fig. 2 | *Classification and labelling can be linked to a specific composition available in section 1.2 through the "related composition" field [17].*

for CLP notification. The first new field is in section 2.1 "Classification and labelling according to GHS" where nanomaterial can be selected as the "form of the substance" and the second is the addition of nanomaterial in the list of options for the form of a substance in section 4.1 "Appearance/physical state/colour/" *(Figure 1* and *2)*.

CONCLUSIONS

Majority of nanomaterials currently on the market seems to be produced together with the respective bulk substance. Therefore they are covered by the CLP and REACH obligations. Although there are currently no provisions in EU legislation that refer explicitly to nanomaterials, legislation on chemicals covers in principle the potential health, safety and environmental risks in relation to nanomaterials.

However, since the REACH and CLP Regulations are not designed for nanomaterials, the chemical legal framework needs to be examined and further developed with a view to guarantee a powerful level of protection for human health and environment. To put this into effect, the handling of nanomaterials should be dealt with the REACH revision foreseen in 2012 and the CLP one accordingly. The adequacy of available information is one of the key studies which may provide inputs to the Commission services in the review of both legislations.

It is, for example, essential that criteria which are directly linked to the outcome of the test methods are applicable to nanomaterials. The CLP Regulation has to be modified as regards thresholds applied as soon as new information on nanomaterials becomes available.

The considerable quantity of CLP notifications and REACH registrations submitted to ECHA in 2010 will lend a chance to evaluate in 2011 the accessible information on nanomaterials currently on the market. The CLP notifications provide ECHA, independently on volume of manufacture or import, with information on hazardous substances and their forms, including different nanomaterials. Both Regulations also have an obligation for updates in case of changes in conditions. Accordingly the part provided to ECHA on REACH and CLP will make an important contribution to the overall information. The Commission and the EU Agencies have reviewed and will continue to evaluate the applicability and appropriateness of documents supporting CLP Regulation implementation (*e.g.* technical guidance documents) with the aim of considering the peculiar and distinctive properties of existing and future nanomaterials.

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Conflict of interest statement

There are no potential conflicts of interest or any financial or personal relationships with other people or organizations that could inappropriately bias conduct and findings of this study.

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CLP Regulation and the transport of dangerous goods

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Summary. Regulations concerning different modes of transport of dangerous goods are well harmonized at global level: they were then looked at as a model for developing Globally Harmonized System of Classification and Labelling of Chemicals (GHS), (on which CLP Regulations is based). Transport regulations do not cover some hazard classes, such as germ cell mutagenicity, carcinogenicity, reproductive toxicity, having been evaluated that such hazards are not relevant in transport because in general, in case of accident, no repeated and prolonged exposure takes place. Other differences with CLP Regulation are related to the use of "building block approach". Transport labels, which were used as a basis for GHS, can be used, instead of CLP pictograms, on packages during transport.

Key words: GHS, CLP Regulation, UN Recommendations, transport of dangerous goods, classification, harmonization, labelling.

Riassunto *(Il Regolamento CLP e il trasporto di merci pericolose)*. Le regolamentazioni concernenti le diverse modalità di trasporto di merci pericolose sono ben armonizzate a livello globale: di conseguenza sono state prese a modello per sviluppare il *Globally Harmonized System of Classification and Labelling of Chemicals* (GHS), (sul quale è fondato il Regolamento CLP). Le regolamentazioni sul trasporto non prendono in considerazione alcune classi di pericolo, quali la mutagenicità sulle cellule germinali, la cancerogenicità, la tossicità per la riproduzione, dal momento che tali pericoli non sono considerati rilevanti per il trasporto, poiché in genere, in caso di incidente, non si è in presenza di esposizioni ripetute e prolungate. Altre differenze col Regolamento CLP derivano dall'utilizzo del *building bloch approach*. Le etichette del trasporto, sulle quali si è basato il GHS, possono essere usate, sui colli in corso di trasporto, in sostituzione dei pittogrammi CLP.

Parole chiave: GHS, Regolamento CLP, Raccomandazioni ONU, trasporto merci pericolose, classificazione, armonizzazione, etichettatura.

THE CONCEPT OF HARMONIZATION

In order to discuss the relationship among CLP Regulation [1] and transport regulations it is necessary to refer to the process of harmonization started at United Nations Conference on Environment and Development (UNCED) in 1992 and completed in 2003 with the publication of the first edition of the Globally Harmonized System of the Classification and Labelling of Chemicals (GHS) [2].

The work on GHS began with the premise that existing systems should be harmonized in order to develop a single, globally harmonized system to address classification and labelling of chemicals in all sectors (workplace, consumer, transport).

Harmonization in transport

It has to be underlined that the concept of harmonization is certainly not a new one.

In particular, as far as the transport regulations are concerned, harmonization among the different modes of transport was largely achieved around the world.

In 1956 the first version of the "Recommendation on the Transport of Dangerous Goods" [3], prepared by the United Nations Economic and Social Council (ECOSOC)'s Committee of Expert on the Transport of Dangerous Goods, was published.

At its nineteenth session (2-10 December 1996) the Committee adopted a revised version of the Recommendations, in the form of "Model Regulations", in order to facilitate its direct integration into all modal, national and international regulations.

These Recommendations, which contain a very detailed set of criteria for classification and labelling of dangerous goods[1] were (and are) then addressed to governments and international organizations responsible for regulating the transport of dangerous goods in order to ensure the safety of people, property and the environment and they.

It was (and is) then expected that governments and international organizations, when preparing or revis-

[1] *In transport regulations dangerous goods cover substances (including mixtures and solution and wastes) and articles containing dangerous substances*

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ing their regulations will conform to the principles laid down in these Recommendations – Model Regulations.

And indeed, looking at the main regulations covering the transport of dangerous goods, such as:

- IMDG Code (international transport by sea);
- ICAO Technical Instructions (international transport by air);
- ADR (European transport by road);
- RID (European transport by rail);
- ADN (European transport by inland waterways);

it can be easily verified that the requirements concerning aspects common to all the modes of transport (such as packaging, documentation, and, of course, classification and labelling of dangerous goods) are largely harmonized.

Transport system as a model

It was then recognized that the transport sector could be referred to as model for the harmonization: harmonization which had not been achieved at global level, in terms of classification and labelling, in the workplace or consumer or others sectors.

In particular the GHS has mutuated from the transport regulations the criteria for classification of substances which are characterized by physical hazards, *i.e.*:

- explosives;
- gases;
- flammable substances and aerosols;
- oxidizing substances;
- pyrophoric substances;
- self-reactive substances;
- substances which, in contact with water, emit flammable gases;
- organic peroxides;
- corrosive to metals.

It has to be noted that such criteria are mainly based on the results of tests performed in accordance with the procedures defined in the *Manual of Tests and Criteria* annexed to the UN Recommendations.

THE RESPONSIBLE BODIES

The Recommendations on the transport of dangerous goods were developed and amended by the Committee of Expert on the Transport of Dangerous Goods.

The members of the Committee were experts from different countries (the countries were identified by the ECOSOC); experts from other countries and from NGOs (non-governmental organizations) also attended the meeting without the right of vote.

Every two years (following intermediate meetings: one every six months) the Recommendations were amended to take care of the developments in technology and the needs of the users.

Taking care of this situation, it was decided to establish a similar body for the GHS.

With the Resolution 1999/65 of 26 October 1999 of ECOSOC it was decide to establish a Committee of Experts on the Transport of Dangerous Goods and on the Globally Harmonized System of Classification and Labelling of Chemicals, which is responsible for the planning and the approval of the work of two SubCommittees:

- the SubCommittee of Experts on the Transport of Dangerous Goods (UNSCETDG);
- the SubCommittee of Experts on the Globally Harmonized System of Classification and Labelling of Chemicals (UNSCEGHS);

both working in the same way as the previous Committee of Expert on the Transport of Dangerous Goods.

The GHS is then amended every two years on the basis of the proposals discussed in the UNSCEGHS.

When, for a proposed amendment concerning physical hazards, there is the necessity for a detailed technical discussion, the UNSCETDG is generally charged for such a work, due to the fact that it was recognized that the UNSCETDG has the necessary competence for dealing with physical hazards.

This structure allows that the amendments to GHS are evaluated in parallel by the UNSCETDG so that transport regulations are harmonized with GHS.

Looking at CLP Regulation, it has to be noted that, for the moment, after his publication at the end of 2008, and notwithstanding the publication of 3rd and 4th edition of GHS, CLP Regulation is still based on the 2nd edition of GHS.

TRANSPORT REGULATIONS AND CLP (CLASSIFICATION)

The criteria for classification in the transport regulations are in line with GHS and then, as far as the Regulation (EC) 1272/2008 (CLP) is harmonized with GHS, transport regulations are generally harmonized with CLP.

However, on the basis of the "building block approach" (see paragraph 1.1.3.1.5.1 of the GHS), transport regulations do not cover all the hazards classes of the GHS, neither all the hazards classes of CLP, as it can be seen by looking at *Table 1*.

Health hazards

The main difference is concerning the health hazards.

In transport regulations hazards such as germ cell mutagenicity, carcinogenicity, reproductive toxicity, etc., are not considered.

The reason for that can be found in the initial approach used for defining the relevant hazards in the transport sector.

It was assumed that the hazards from transport, due to the specific conditions of the transport itself (a transport unit in movement, a quantity of dangerous goods "limited" with respect to the quantity available in fixed installation, an easier way for people of going far from the accident), are characterized by a "short" exposure of the people involved in some accident.

And it was then assumed that hazards like carcinogenicity, etc., can be a serious problem only in the case of repeated and prolonged exposure (which, as said, is not the case for transport accident).

Table 1 | *Comparison of hazard classes in CLP and in transport regulations*

CLP classification	Transport classification (UN Recommendations)
Unstable explosives	*Not allowed for transport*
Explosives Division 1.1, 1.2, 1.3, 1.4, 1.5, 1.6	Class 1, Division 1.1, 1.2, 1.3, 1.4, 1.5, 1.6
Flammable gases, Category 1	Class 2, Division 2.1
Flammable gases, Category 2	*No dangerous*
Flammable aerosols, Category 1, 2	Class 2
Oxidizing gases, Category 1	Class 2, Division 2.2
Gases under pressure	Class 2, Division 2.2
Flammable liquids, Category 1, 2, 3	Class 3, Packing group I, II, III
Flammable liquids, Category 4	*No dangerous*
Flammable solids, Category 1, 2	Class 4, Division 4.1, Packing group II, III
Self-reactive substances and mixtures, Type A	*Class 4, Division 4.1, Type A Not allowed for transport*
Self-reactive substances and mixtures, Type B, C, D, E, F, G	Class 4, Division 4.1, Type B, C, D, E, F, G
Pyrophoric liquids, Category 1	Class 4, Division 4.2, Packing group I
Pyrophoric solids, Category 1	Class 4, Division 4.2, Packing group I
Self-heating substances and mixtures, Category 1, 2	Class 4, Division 4.2, Packing group II, III
Substances and mixtures which, in contact with water, emit flammable gases, Category 1, 2, 3	Class 4, Division 4.3, Packing group I, II, III
Oxidizing liquids, Category 1, 2, 3	Class 5, Division 5.1, Packing group I, II, III
Oxidizing solids, Category 1, 2, 3	Class 5, Division 5.1, Packing group I, II, III
Organic peroxides, Type A	*Class 5, Division 5.2, Type A Not allowed for transport*
Organic peroxides, Type B, C, D, E, F, G	Class 5, Division 5.2, Type B, C, D, E, F, G
Corrosive to metals, Category 1	Class 8, Packing group III
Acute toxicity, Category 1, 2, 3	Class 6, Division 6.1, Packing group I, II, III
Acute toxicity, Category 4, 5	*No dangerous*
Skin corrosion/irritation, Category 1, Sub-category 1A, 1B, 1C	Class 8, Packing group I, II, III
Skin corrosion/irritation, Category 2, 3	*No dangerous*
Serious eye damage/eye irritation, Category 1, 2A, 2B	*No dangerous*
Respiratory or skin sensitization, Category 1	*No dangerous*
Germ cell mutagenicity, Category 1A, 1B, 2	*No dangerous*
Carcinogenicity, Category 1A, 1B, 2	*No dangerous*
Reproductive toxicity, Category 1A, 1B, 2	*No dangerous*
Specific target organ toxicity single exposure, Category 1, 2, 3	*No dangerous*
Specific target organ toxicity repeated exposure, Category 1, 2	*No dangerous*
Aspiration hazard, Category 1, 2	*No dangerous*
Hazardous to the aquatic environment, Category acute 1, chronic 1, chronic 2	Class 9
Hazardous to the aquatic environment, Category acute 2, acute 3, chronic 3, chronic 4	*No dangerous*
Hazardous to the ozone layer	*No dangerous*

It has to be noted that these assumptions (which however have never been consolidated in a formal text) have been questioned in the last years.

Reference was made, for example, to some results which give evidence to the development of cancer after a single exposure.

And reference was made to the fact that in transport regulations substances like asbestos and PCB are however classified as dangerous substances (in Class 9: miscellaneous dangerous substances and articles).

Some countries (in particular Italy) have asked for inclusion of carcinogens, mutagens, etc. in the transport regulations, but, up to now, the majority of the members of the UNSCETDG didn't agree with such proposal.

For the health hazards covered by transport regulations (*i.e.* acute toxicity and skin corrosion) the harmonization with CLP however is not complete.

First of all, on the basis of the "building block approach", the hazard from acute toxicity is limited to Categories 1, 2 and 3 (and, as recognized by GHS, the classification for toxic by inhalation substances

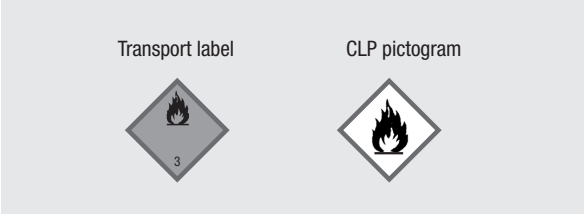

Fig. 1 | *Transport/CLP pictograms.*

is based, in transport regulation, also on the evaluation of volatility).

As far as corrosion/irritation is concerned, up to now transport regulation are considering only skin corrosion and the criteria are only based on test results: however discussion is going on in the UNSCETDG to achieve a higher level of harmonization with GHS/CLP.

Substances hazardous to the environment

The situation for substances hazardous to the environment is still evolving towards a higher level of harmonization, the delay in such process being caused by the pre-existing major differences between modal regulations.

One main difference among CLP and transport regulations, looking to the substances hazardous to the aquatic environment, is deriving from the application of the "building block approach": only Category acute 1, chronic 1 and chronic 2 are covered by transport regulations.

On the other side it is relevant to note that, in order to facilitate the duties of shippers of dangerous goods, in the European land transport regulations (ADR/RID/ADN) a clear reference is made to CLP so that a substance classified as hazardous to the environment in CLP is classified in the same way in ADR/RID/ADN.

It has also to be noted that up to now no reference is made in transport regulations to substances hazardous to the ozone layer.

Physical hazards

As mentioned before, the criteria for physical hazards contained in the GHS have been derived by the criteria developed in the transport sector. That entails that there was no need, in the transport sector, for many changes in order to harmonize with GHS.

Some differences in respect of CLP are deriving, also for physical hazards from "building block approach". For example, in the case of flammable liquids, only Categories 1, 2 and 3 are covered in transport regulations.

Other hazards

It is relevant to note that in transport regulation other hazards are considered, which are not covered by CLP (and GHS).

It is the case of:
- infectious substances;
- radioactive materials;
- other dangerous substances (such as: elevated temperature substances, genetically modified microorganism, lithium batteries, etc.).

TRANSPORT REGULATIONS AND IMPLEMENTATION OF CLP (LABELLING)

While labels, according to CLP, are meant to contain several information (pictograms, signal words, hazard and precautionary statements, etc.), in the "language" of transport regulations labels are what in CLP is defined as a pictogram.

Due to the fact that CLP pictograms were derived from the transport label (of course for hazard classes and categories covered by transport regulations), there was no need to change the existing system of labelling for the transport.

So, in the case of a packaging used for transport, for hazard classes and categories covered by transport regulations, the transport label is used and the CLP pictogram is unnecessary.

For example, on a drum containing flammable liquids (Category 1, 2 or 3), the transport label shall be placed on a drum: while the CLP pictogram is not requested *(Figure 1)*.

Conflict of interest statement

There are no potential conflicts of interest or any financial or personal relationships with other people or organizations that could inappropriately bias conduct and findings of this study.

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CLP Regulation and REACH Regulation: links, implementation and control in Italy

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Summary. In the last years the European policy for the management of chemicals is deeply changed after entering into force of the European Regulations (EC) no. 1907/2006 and (EC) no. 1272/2008. The implementation of the two Regulations requests a strong effort both from the enterprises and from national and regional institutions. The activities already realised or that are planned for the implementation of one of them could support the implementation of the other one. The crucial point is the creation of the surveillance coordination through a network that involves also the professional figures currently present in the border areas in order to check the compliance with the European legislation of substances on their own, in mixtures or in articles before they are put on European market.

Key words: REACH, CLP, enforcement, substances, implementation.

Riassunto *(Regolamento CLP e Regolamento REACH: collegamenti, attuazione e controllo in Italia)*. Negli ultimi anni la politica europea di gestione delle sostanze chimiche è profondamente cambiata con l'entrata in vigore dei Regolamenti europei (CE) no. 1907/2006 e (CE) no. 1272/2008. L'attuazione dei due Regolamenti richiede un grande sforzo sia da parte delle imprese che delle istituzioni nazionali e regionali. In particolare, si sottolinea che alcune attività poste in essere per l'attuazione di uno di essi sono a sostegno anche dell'implementazione dell'altro. Punto cruciale è la realizzazione del coordinamento in materia di vigilanza per mezzo della rete di controlli che coinvolga anche le figure professionali attualmente presenti nell'area di frontiera, al fine di verificare la conformità alle norme europee delle sostanze in quanto tali o contenute in miscele o articoli prima della loro immissione sul mercato europeo.

Parole chiave: REACH, CLP, attuazione, sostanze chimiche, controllo.

INTRODUCTION

In recent years the European politic management of chemicals is deeply changed. From one side the new European Regulation (EC) no. 1907/2006 [1] concerning the registration, the evaluation and the authorisation of chemicals (REACH), has created a new European system of chemical management that has the main target to increase the knowledge of the risks linked to the majority of substances already put on the market. The registration system created by REACH asks the same information both for a substance already on the market at June 2008 (called phase-in substance) and for a new substance at June 2008 (called non-phase-in substance), anyway it is foreseen a transitional period for the registration of phase-in substances. The REACH Regulation introduces an authorisation procedure for the substances of very high concern that are listed in Annex XIV to REACH and it collects in its Annex XVII the restriction measures already foreseen from the previous directive on this matter (Directive 76/769/EEC [2]). On the other side the European Community is committed to contribute to the global harmonisation of the criteria for classification and labelling of substances and mixtures within the United Nations [3]. This commitment has requested a regulatory activity aiming at transferring the new criteria defined at the United Nations level to the European existing system on classification and labelling. The European Regulation (EC) no. 1272/2008 [4] concerning the new criteria of classification, labelling and packaging of substances and mixtures, called CLP Regulation, indicates in the transitional provisions that the new rules are applied to substances from 1 December 2010 and then to mixtures from 1 June 2015.

LINKS BETWEEN THE REACH AND CLP REGULATIONS

There are several links between the REACH and the CLP Regulations because some dispositions under REACH are applied whether or not the substance is classified and how it is classified.

These common points are described below:

- the first registration deadline was the 1 December 2010 for manufactures and importers of the substances manufactured or imported above 1

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tonne/year and classified according to the CLP Regulation as carcinogenic, mutagenic or toxic to reproduction (CMR Cat. 1A&1B). The 1 December was also the deadline for manufactures and importers of the substances manufactured or imported above 100 tonne/year and very toxic for acquatic environmental;
- a Member State or the European Commission can begin the formal identification process of a substance as very high concern (SVHC) if it is classified as carcinogenic, mutagenic, or toxic for reproduction;
- some restrictions in Annex XVII are related to substances having a specific classification. For example substances or mixtures classified can not be used in tricks and jokes (point 3 of Annex XVII), or the carcinogenic substances on their own and in mixtures can not be placed on the market for sale to the general public in individual concentration equal to or greater in quantity 0.1% w/w;
- when a substance is manufactured or imported above 10 tonn/year the registrant has to conduct a risk assessment. The first step of this assessment is to evaluate whether or not the substance meets the CLP criteria;
- the obligation to supply a safety data sheet (SDS) set forth in the Article 31 of REACH Regulation is linked to the substance and mixture classification;
- a Member State until 2015 or the European Chemical Agency (ECHA) from 2015 can permit the use of an alternative name of a substance present in a mixture upon request of a company which indicates that an economic damage could occur if known the chemical name of the substance. When the authorisation is granted the supplier of the mixture can use the alternative name instead of the chemical name in the mixture SDS as well as on the mixture label. This permission can be granted only if the substance is classified in specific categories and classes set forth in Article 24 of CLP Regulation;
- in the "hazard identification" and "composition" sections of a SDS the information have to be reported on the basis of the legislation concerning the classification currently in force. The Annex II of the REACH Regulation was modified recently by the Regulation (EC) no. 453/2010 [5], in particular this latter regulation specifies that in the "hazard identification" section the substance classification has to be indicated with the rules set forth both in CLP Regulation and in the Directive (EEC) no. 67/548 Dangerous Substance Directive - (DSD) [6] since 1 December 2010, instead the mixture classification has to be reported in the SDS with the rules set forth in Directive (EC) no. 1999/45 [7] (Dangerous Preparation Directive - DPD) until 2015. However a ingredient of a mixture has to be reported in the "composition" section with the rules set forth both in the DPD and in the CLP Regulation unless derogations. This double indication has to be applied for five years (1 December 2010 - 1 June 2015) and it is necessary in order to pass gradually from the rules of the DPD to the CLP ones.

On the other way round, in the CLP Regulation there are some mandatory requests based on what it is the substance or mixture status under REACH. Below some examples are reported:
- it is mandatory to notify to the ECHA's Inventory on the classification and labelling the substances that have to be registered under the REACH Regulation. Therefore even if the substance does not meet the criteria set forth in the CLP the notification has to be submitted together with the justification why the eco-toxicological, toxicological or chemical-physical data do not match the CLP criteria;
- where during the REACH registration process the ECHA has permitted the use of a "alternative designation" for a substance because the company indicated that an economic damage would occur if known the chemical name, the alternative designation can be used in the SDS and in the label, without submitting the specific request set forth in Article 24 of CLP (see Article 24, paragraph 6).

IMPLEMENTATION OF THE REACH AND CLP REGULATIONS IN ITALY

As mentioned above the two REACH and CLP Regulations are linked each other and they both modify the European chemical management policy, therefore both the national activities and the industries actions already realised or planned to be carried out in the future for the implementation of one of them could support the implementation of the other.

The implementation of the two Regulations needs a huge effort from the enterprises because, in particular, the REACH is based on the principle that industry should manufacture, import, use or place on the market substances ensuring that, under reasonably foreseeable conditions, the human health and the environment are not adversely affected. Instead the new CLP criteria of the classification and labelling require the enterprises to update in a short time for example the software used to determinate classification, labelling or to the safety signs on the workplace. In addition the enterprises should respect the provisions of other pieces of legislation linked with the classification criteria and that now can have an impact on some substances or mixtures that before were out of the scope.

On the other hand also the national institutions are called to do a strong effort related to the implementation of the two regulations. Indeed, even if a European Regulation does not need a national application law the Member State has to create specific instruments to assure the implementation of the new European rules, and it has to evaluate whether some economic resources are needed.

The Italian institutions are committed for the

REACH implementation since 2007. The instruments that were created to implement the REACH will be useful also for the CLP Regulation. With the law no. 46/2007 [8] the Ministry of Health was designated as Competent Authority (CA) for REACH Regulation instead the legal basis for designation of CLP Competent Authority does not exist yet. The REACH CA cooperates with the Ministry of Environmental and the Ministry of Economic Development and receives the technical support from the National Centre for Chemical Substances (CSC) located within the National Institute of Health in Italy (ISS) and from the National Institute of Environmental Protection and Research (ISPRA). It is important to underline that the CSC was instituted in order to have a national reference point which give scientific support in the framework of REACH implementation. Other than the above mentioned national institutions, also the Regional level supports the REACH implementation. These different administrations are coordinated by a coordination technical committee, formally defined [9, 10]. The Committee meetings are planned at least three time per year and the Committee has 6 working groups:

- surveillance network;
- support to ECHA committees activities;
- meet with enterprises;
- nanomaterials;
- support to Committee procedure set forth in REACH Article 133;
- information and trainings.

In order to support activities concerning the inspections the Regions have as focal point a technical groups within inter-regional prevention management (CIP).

Furthermore the Italian Law no. 46/2007 assigned for each year the financial resources to every Ministries and Institutes above mentioned.

Another instrument defined in order to implement the REACH Regulation is the creation of a surveillance network. This network is based on the coordination between the Ministry of Health and the Regions and it is based on the State-Regions Agreement [11]. According to this Agreement every Region or autonomous Province has to implement the Agreement in his legal organisation. At the moment, 13 Regions and 1 autonomous Province have already done this step and they have individuated the "control authority" that will be dedicated to the inspections in his own territory. As interesting element, most of these Regions have underlined that the REACH control authorities it is also the control authorities implementing the CLP Regulation.

A key element of the surveillance network creation is to clarify the involvement of the different border authorities in the REACH implementation.

Another specific instrument necessary to implement the two regulations at national level is an appropriate penalties system which has to ensure transparency, impartiality and consistency of the single Member State enforcement activities, with a view to imposing effective, proportionate and dissuasive penalties for REACH and CLP non-compliances. In Italy the national Decree no. 133/2009 [12] sets up the penalties system for the REACH non-compliances. The Decree establishing the penalties for CLP non-compliances has not been emanated yet, however the legislative process is ongoing.

The penalties for the non-compliance with REACH provisions are both administrative and criminal and this is foreseen also for the CLP penalties system. The maximum level of the REACH sanctions is related to non-compliance with the authorisation and restriction provisions as it is foreseen the prison until three months. Different administrative sanction levels are foreseen in the Decree no. 133/2009 for others REACH non-compliances. Some examples are reported below:

- when a company manufactures, imports or puts on the market a substance not registered, the penalties level is set up in the range 15 000 – 90 000 €, while whether the substance without registration is an intermediate the level goes down to 10 000 – 60 000 €;
- the highest penalties level (15 000 – 90 000 €) is set up for the absence of the communication concerning the updating on tonnage of a notified substance under Directive EEC no. 67/548 (DSD);
- in the Decree no. 133/2009 the penalties are in the range 15 000 – 90 000 € foreseen for the violation to the obligations detailed in the REACH article 14, concerning the chemical safety report and duty to apply and recommend risk reduction measures;
- unless it constitutes a criminal offence, the registrant who carries out tests on vertebrate animals that are not absolutely necessary and fails to introduce measures for limiting the useless repetition of other tests, in accordance with REACH Article 25 paragraph 1, shall incur a fine within the range 10 000 – 60 000 €;
- also the violation of the obligations detailed in Articles 7, 31, 32, 33, 34, 35 and 36 of the REACH, in respect with the information in the supply chain is sanctioned at different levels, from 3000 – 18 000 € if the SDS is not in Italian language up to 10 000 – 60 000 € if a supplier of a substance or a mixture does not supply SDS in accordance with Articles 31 and 32.

In the context of the adaptation of the previous national legislation on chemicals according to the new REACH provisions, it has been necessary to modify the national Decree no. 52/97 that implemented the Directive (EEC) 67/548. The main change was the deletion of the national notification unit, because the registrations of chemicals are now collected by ECHA. The modification has been done through the Decree no. 145/2008 which also introduced a new element useful for both the REACH and the CLP inspections. This element indicates the need to establish a fee to be applied to the inspected company. This choice has the following justification: in the past the inspections were conducted by the Ministry of Health and the ISS to verify the compliance with

the rules of the substances and mixture classification and the labelling and with the notification duty under Directive (EEC) no. 67/548 and the financial coverage was assured by the notification fees. With the entering into force of the REACH Regulation the registration fees are managed by ECHA, thus the future inspections concerning the respect of the CLP and REACH provisions are not foreseen to be financed. The Italian Decree no. 145/2008 introduces the fees application concept on inspections. The fees are now established in a default amount of 2000 €, but a future Ministerial Decree will specify the criteria to apply the fees.

In order to implement the two regulations other activities have been done with the cooperation among the different institutions indicated in the national Decree of the 22 November 2007. Below these activities are briefly described:

- official communications to clear some interpretation of the two regulations;
- organising conferences and workshops;
- organising trainings for inspectors and public administrators;
- management of the national helpdesk. The Ministry of the Economic Development is responsible of the REACH helpdesk;
- support to enterprises by collecting practical issues and sharing views on possible solutions with category associations;
- the Ministry of the Economic Development has promoted by national Decree of the 19 March 2009 [13] economic incentives to the industries having a project of research and development in order to substitute the substances that meet the criteria set forth in Article 57 of REACH;
- the REACH CA and the Ministry of environment have invested financial resources to improve the knowledge on substance having endocrine disrupting properties:
- evaluation of ECHA's draft decisions concerning the completeness check of a registration dossier and the testing proposal. The Centro Nazionale Sostanze Chimiche (CSC) and ISPRA support the REACH CA in this task through a defined procedure;
- creation and management of the database of models for substance SDSs. The CA offers a free support to elaborate a substance SDS. The SDS models are available in the web site of the Ministry of Health, in the "chemicals safety" section (www.salute.gov.it/sicurezzaChimica/sicurezzaChimica.jsp). Obviously the supplier of a substance or a mixture remains responsible of the SDS but the database helps to elaborate the SDS;
- activities concerning the dissemination of the information by on-line magazines. For example the magazine edited since 2007 by the Ministry of Economic Development "REACH-on digit" contains useful topics to support the enterprises. Since 2009 the Ministry of Environment has been publishing a magazine *Bolletino di informazione sostanze chimiche – ambiente e salute* which has as main target the general public;
- promoting master on REACH. The Ministry of Health as CA collaborated with Ministry of Research and University in order to establish common topics in the different Master projects [14]. Few masters have already been hold and other universities are planning to start new ones. Until now the masters have offered a high level education in the risk assessment field, anyway it is important to disseminate information about the socio-economic analysis criteria. The REACH CA supports these initiatives with some economic resources;
- furthermore, some REACH and CLP implementation activities have involved also the school world. Promoting the curiosity in the young students could be a way to obtain in the future an higher number of experts in risk management of chemicals or experts in socio-economic analysis. On the other hand the promotion of the knowledge of the key points concerning the hazard and risk of the chemicals or the knowledge of the rights to have more information about articles could create citizens more aware that their behaviour influences the status of their own health and the quality of the environment. A training for teachers from every Region of Italy has been hold on December 2010. Thus they will disseminate the key information about the REACH and CLP Regulations. Also for this project financial resources have been given by REACH CA.

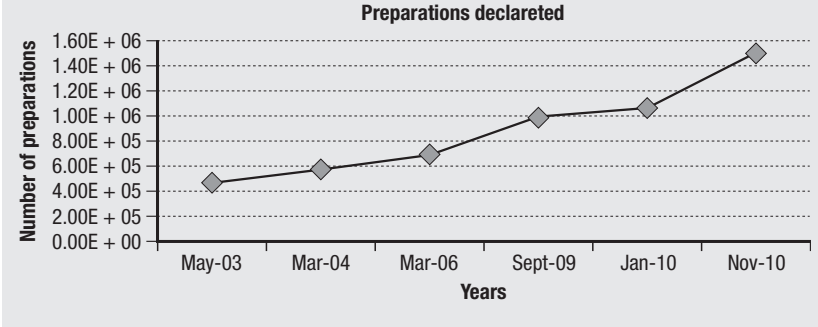

Fig. 1 | *In the graph the mixtures declareted up to November 2010 in the archive are reported.*

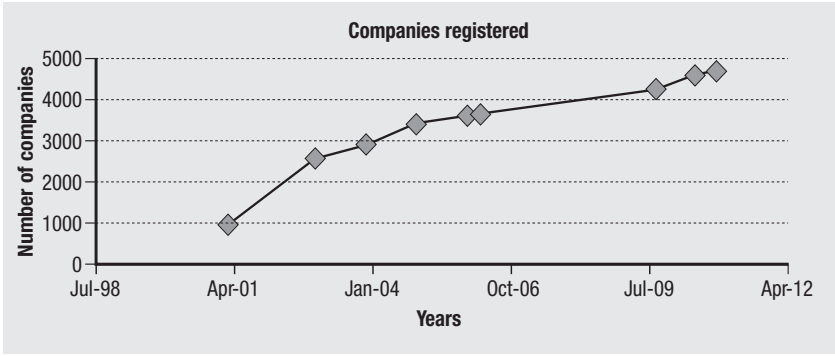

Fig. 2 | *The figure shows the number of companies that have submitted the notifications until now.*

The picture drawn above shows the infrastructure created at national level to support REACH implementation. Of course this infrastructure will work also to support the CLP implementation: for example the REACH technical committee of coordination could be the meeting point to discuss the management of the CLP issues and agree possible solutions. However, as anticipated previously, at while the REACH CA has been appointed (Ministry of Health), the CA for CLP has not been designated yet. For the sake of continuity, who managed the old classification and labelling legislation should continue to manage the same matter.

Even in absence of an official appointment, several activities related to CLP implementation have been already carried out in Italy. To give an example, the CLP helpdesk is managed by the CSC and is currently working.

The collection of useful information to support anti-poisoning centres activities set forth in Article 45 of the CLP Regulation is based on dangerous preparation archive created in the 2000 under the Directive 1999/45/EC [15]. Up to now, one million and half notifications on dangerous mixtures and detergents (independently from their classification) have been submitted by about five thousand companies *(Figure 1* and *Figure 2)*.

Furthermore the access to the database have been granted to 9 Italian anti-poisoning centres.

The information required for the notification are listed in the *Table 1*.

Table 1 | *Information required for the notification to preparations archive*

Information required	Mandatory (yes/no)
Name/address, Tel./Fax., e-mail of registrant	yes
Trade name of the products	yes
Intended uses	yes
Physical state	yes
Other physico-chemical properties	no
Full quali-quantitative chemical composition	yes
C&L	no
Packaging description	no

This database is going to be revised since the European Commission is working to define on harmonized core set data and a common format that the importers and downstream users will have to use.

A good example of collaboration between different levels that work to ensure safety of products on the market and the respect of the chemical legislation is the Italian activity on methanol.

In the 2007 after an accident occurred to a consumer after skin application of a mixture of unknown composition, the anti-poisoning centre of Milan (Niguarda Ca'Grande Hospital) communicated to the ISS and the Ministry of Health that this dangerous preparation was not in the archive. The effects that the patient showed were after attributed to the methanol action. Taking into consideration that other cases were later identified also by other anti-poisoning centres, that a national law of 1982 prohibits the presence of methanol in detergents, cosmetics and paints, Italy would like to promote a European action on the basis of a socio-economic and a risk management option analyses. Italy has just committed to submit a proposal for a new classification of the methanol as toxic for reproduction (development) Category 1B.

The CSC offers different implementation tools which are present in its website (www.iss.it/cnsc/):

- the 1st tool is a database which contains substances within the European inventories and gives information on the harmonised classification according to both the DPD and CLP criteria and, where present, the database gives information regarding the restrictions and/or authorisation set forth in REACH;
- the 2nd tool is a link to German converter from that can be used to establish a proposed "new" GHS-compliant classification based on the previous classification in line with the guideline relating to the relevant substance or mixture;
- the 3rd tool is a database that collects the most recent literature search about carcinogenic and sensitizer substances.

ITALIAN INSPECTION NETWORK FOR REACH AND CLP

The REACH and CLP inspections could be either carried out together or separately, thus the Italian en-

Table 2 | *Regionall/Provincial control Authorities for REACH and CLP Regulation*

Regions / autonomous Province	Adoption	Legal act	Control Authority for REACH	Indication concerning Control Authority for CLP
Abruzzo [17]	yes	*DGR n. 242 del 22/03/2010	Direzione Politiche della Salute, Regione Abruzzo	yes
Basilicata	no			
Bolzano	no			
Calabria [18]	yes	DGR n. 26 del 28/01/2010	Dipartimento Regionale Tutela della Salute e Politiche Sanitarie, Regione Calabria	yes
Campania [19]	yes	DGR n. 372 del 23/03/2010	Settore Assistenza Sanitaria Igiene e Sanità Pubblica Igiene e Medicina del lavoro dell'Area di Coordinamento Assistenza Sanitaria dell'Assessorato alla Sanità, Regione Campania	yes
Friuli Venezia-Giulia	no			
Emilia Romagna [20]	yes	DGR n. 356 del 08/02/2010	Servizio Sanità Pubblica della Direzione Generale Sanità e Politiche Sociali, Regione Emilia Romagna	yes
Lazio [21]	yes	DGR n. 272 del 01/06/2010	Direzione Regionale Politiche della Prevenzione e dell'Assistenza Sanitaria Territoriale, Regiona Lazio	yes
Liguria [22]	yes	DGR n. 397 del 05/03/2010	Dipartimento Salute e Servizi Sociali, Regione Liguria	-
Lombardia	no			
Marche [23]	yes	DGR n. 562 del 15/03/2010	Posizione di Funzione Sanità Pubblica del Servizio Salute, Regione Marche	yes
Molise	no			
Piemonte [24]	yes	DGR n. 30-13526 del 16/03/2010	Direzione Sanità, Regione Piemonte	yes
Puglia [25]	yes	DGR n. 729 del 15/03/2010	Servizio Programmazione Assistenza Territoriale Prevenzione dell'Assessorato alle Politiche per la Salute, Regione Puglia (Autorità Competente per i controlli) Direttore Generale dell'Azienda Sanitaria Locale (Autorità Sanitaria Locale)	yes
Sardegna	no			
Sicilia	Working in progress			
Toscana [26]	yes	DGR n. 346 del 22/03/2010	Direzione Generale Diritto alla Salute e Politiche di Solidarietà – Regione Toscana	yes
Trento [27]	yes	**DGP n. 848 del 16/04/2010	Direzione Igiene e Sanità Pubblica della Azienda Sanitaria Provinciale	-
Umbria [28]	yes	DGR n. 80 del 25/01/2010	Direzione regionale Sanità e Servizi Sociali Regione Umbria	-
Valle d'Aosta [29]	yes	DGR n. 1298 del 14/05/2010	Assessorato della Sanità salute e politiche sociali Servizio igiene e sanità pubblica, veterinaria e degli ambienti di lavoro	yes
Veneto [30]	yes	DGR n. 523 del 02/03/2010	Direzione Regionale Prevenzione Regione Veneto	-

**DGR (Delibera della Giunta Regionale): regional legal act.*
***DGP (Delibera della Giunta Provinciale): provincial legal act.*

forcement authorities for REACH and CLP are not necessary the same. In Italy while the controls on classification and labelling of substances and mixtures are a duty of the Regions since 1978 (Law 23 December 1978 no. 833) [16], it was necessary to establish an agreement between State and Regions in order to define the control Authorities for REACH. This agreement indicates that the Regions, as it was for the old legislation on chemicals enforcement, have a main role for REACH inspections.

Different legal steps are needed to define enforcement control authorities for REACH at regional level. At present 13 Regions and 1 Province autonomous have already been appointed it and in most cases this authority is also in charge of CLP controls *(Table 2)*.

It is important the transparency of these appointments in order to make easy the improvement of the coordination promoted from the ECHA Forum with

respect to both the other EU Member States enforcement authorities and to the national ones, to the national CA and ultimately to the inspectors.

The Competent Authority (Ministry of Health) has supported Regions with financial resources for the establishment of regional inspectors accesses to the REACH-IT system of ECHA. Furthermore the CA has organized two trainings for trainers who will then in turn train REACH inspectors. After these national events three macro-regional events (north, south, centre of Italy) were held for inspectors, with a financial support of the CA.

To complete the picture, the inspections were also performed at central level, according to the ENFORCE 1 program of ECHA Forum and will continue to be conducted with the participation of the CA. In some of these central inspections regional inspectors can join the inspection team in order to make practical experience. In the future most part of the REACH and CLP inspections will be conducted by the regional authorities.

CONCLUSIONS

In light of the new system of management of chemicals as substance on their own, in mixtures or in articles a huge effort has been done at both institutional level and enterprise level. Industries need to be supported in order to make them aware of the new rules and the upcoming deadlines. It is important to underline that the Italian landscape is populated mainly by medium and small enterprises that more than ever need to be supported by new professional figures, category associations and public institutions in order to be competitive and correctly apply the new chemicals legislation. This is the main reason why the Ministry of Health as Competent Authority collaborates with the Ministry of Instruction in order to encourage training activities at different levels. The introduction within the educational system, starting from secondary school up to post-graduate level, of specific courses will have an important impact on creating new resources for both the enterprises and the public institutions and will help to increase the general knowledge and awareness of the general public on this matter.

The coordination of inspections is a crucial point. The first step is to define clearly all inspection network by individuating in each Region and Province autonomous the local enforcement authority. It is important to define the annual inspections national programme according to the future programmes defined by ECHA Forum and taking into consideration the specific territorial needs.

In addition it is necessary to define procedures to involve the control authorities present at the border areas in order to improve the controls on substances, mixtures and articles before they enter the European market.

Finally it is desirable a strong cooperation and an effective management to make all different actors involved both in the implementation and in the enforcement of the REACH and CLP achieving a good functioning of "Italian system" within the European activity on new policy on chemicals management.

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There are no potential conflicts of interest or any financial or personal relationships with other people or organizations that could inappropriately bias conduct and findings of this study.

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CLP activities and control in Ireland

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Summary. The 10th December 2010 marked a new beginning for Regulation (EC) no. 1272/2008 on the classification, labelling and packaging of substances and mixtures (CLP) in Ireland with the start of its *operational phase.* It was on this date that the administrative and enforcement provisions for CLP were encompassed in the new Chemicals Amendment Act, 2010. In this Act, the Health and Safety Authority, known as the "the Authority" is named as Competent Authority (CA) for CLP, along with the Minister for Agriculture, Fisheries and Food, in respect of pesticides and plant protection products and the Beaumont Hospital Board with responsibility for receiving information relating to emergency health response. In practice, the Authority has been *de facto* CA for CLP since its publication on the 31st December 2008, given its role in existing classification and labelling regimes. This article focuses on the work undertaken by the Authority on CLP at a National, European and International level including its implementation, training, helpdesk, guidance, enforcement and awareness raising activities.

Key words: CLP, GHS, enforcement, implementation, Ireland.

Riassunto *(Attività e controllo del CLP in Irlanda)*. Il 10 dicembre 2010 rappresenta in Irlanda un nuovo punto di partenza per il Regolamento 1272/2008 (CLP) con l'inizio della sua "fase operativa". Infatti, a partire da questa data, le disposizioni amministrative e attuative del CLP sono rientrate nel nuovo *Chemicals Amendment Act*, 2010. In questa legge, l'*Health and Safety Authority*, nota come Autorità, viene nominata Autorità Competente per il CLP (CA) insieme con il Ministro per l'agricoltura, la pesca e l'alimentazione (*Minister for Agriculture, Fisheries and Food*), per quanto attiene ai pesticidi e ai prodotti per la protezione delle piante, e il *Beaumont Hospital Board* organismo incaricato di ricevere le informazioni relative a risposte di emergenza sanitaria. In pratica, a partire dalla pubblicazione della legge il 31 dicembre 2008 l'Autorità, in considerazione del suo ruolo nell'attuale sistema di classificazione ed etichettatura, è diventata *de facto* CA per il CLP. Questo articolo presenta le attività intraprese dall'Autorità, relativamente al CLP, a livello nazionale, europeo e internazionale incluse attività di controllo, formazione, *helpdesk*, orientamento, attuazione e sensibilizzazione all'uso.

Parole chiave: CLP, GHS, attuazione, controllo, Irlanda.

INTRODUCTION

It seems appropriate to say that "Rome wasn't built in a day" when it comes to describing the work undertaken by the Health and Safety Authority in Ireland in preparing for Regulation (EC) no. 1272/2008 on the classification, labelling and packaging of substances and mixtures (CLP).

Although a small island on the periphery of Europe, Ireland has a large chemical industry with eight of the top ten pharmaceutical companies based here. This generates over 50 percent of the country's exports, making Ireland the largest net exporter of medicines in the world. It is also an important source of employment having grown from 5200 in 1988 to over 24 000 by 2009 (www.pharmachemicalireland.ie/Sectors/PCI/PCI.nsf/vPages/About_us~industry-profile?). Aside from this large chemical sector, Ireland's chemicals industry is made up of thousands of small and medium enterprises who mostly use or formulate chemicals. Both of these groups are impacted by the changes introduced by Regulation (EC) no. 1272/2008 on the Classification, Labelling and Packaging of substances and mixtures (CLP) on how they classify, label and package their chemical products. These changes are there for companies whether they are manufacturers, importers or users of chemicals. CLP also brings challenges to the Authority and the other Irish CA's with responsibility for regulating it. However, regardless of all the challenges,

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Fig. 1 | *CLP warning sign logo for helpdesk.*

there are also plenty of opportunities and benefits for companies and Authorities too with the introduction of CLP.

THE HEALTH AND SAFETY AUTHORITY

This Agency was established in Ireland in 1989 and employees 186 staff, most of whom are inspectors. In addition to CLP, the Authority has responsibility for the enforcement of occupational safety and health law, promoting and encouraging accident prevention and providing information and advice to all companies, organisations and individuals. It is also the Competent Authority for Regulation (EC) no. 1907/2008 on the registration, evaluation, authorization and restriction of chemicals (REACH) along with other chemicals legislation, dealing with every size of workplace, in every economic sector in Ireland (www.hsa.ie/eng/About_Us). Although the Authority always had a remit for chemicals legislation, its focus for many years was on occupational health and safety law. This changed with the introduction of REACH, which brought the importance of chemicals management in the workplace and its impact on consumers and the environment sharply into focus. This ultimately led to the establishment of a new Chemicals Division within the Authority in 2006, the first Chemicals Act in 2008, and a new strategic focus from 2010. This sent a clear message that chemicals were now clearly within the remit of Authority, as reflected in one of its strategic goals "To promote the safe and sustainable management of chemicals" [1]. The implementation of CLP in Ireland and indeed throughout Europe followed closely the legislative format and processes already developed and established by REACH. For the most part, this made the CLP implementation process in Ireland run more smoothly. However the aligned first registration deadline under REACH and classification and notification deadline under CLP at the end of 2010 did lead to some confusion for Irish stakeholders.

CLP IMPLEMENTATION

The Authority CLP implementation process commenced in January 2006, when its first Globally Harmonized System for the Classification and Labelling of Chemicals (GHS) implementation plan was drafted. This plan outlined who would be affected and the steps the Authority would take towards its implementation. This lead to the first of many successful seminars in May of that year, where invited speakers from the European Commission, the European Chemical Industry Council (CEFIC) and the United Kingdom Health and Safety Executive (HSE) gave a flavour of what could be expected to change in Europe as a result of the GHS. In August of 2006, the much anticipated draft GHS regulation and public consultation process commenced. In early 2007, the GHS implementation work activities began in earnest, having already been identified in the national implementation plan. The Authority incorporated the GHS work activities into its "REACH implementation plan", which then became the "REACH and GHS implementation plan". This was to ensure that the Authority was equally prepared for both REACH and CLP.

The GHS stream within this implementation plan included activities such as the European Council negotiations, guidance development and United Nations work, along with awareness raising activities. The GHS activities remained within this implementation plan until June 2008, when REACH became operational, which also coincided with the end of the CLP negotiations. The Authority's resources were focused towards raising awareness on REACH as this regulation was the priority for Irish Industry. As CLP had not entered into force in 2008, it was deemed too early to commence a full awareness raising effort on CLP. However, 2008 it was still a busy year for the Authority regarding CLP/GHS activities in terms of supporting the development of European Chemicals Agency (ECHA) guidance and finalising the CLP Regulation itself.

It was only when CLP entered into force on the 20th January 2009, that the Authority's activities to provide the necessary support to its Irish Stakeholders increased. It was also clear from the publication of CLP as an official journal, that the Authority had an impending role under CLP and therefore work was required. At a National level, this included training the Authority's chemicals inspectorate, establishing a dedicated Helpdesk, raising awareness and implementing the necessary administrative and enforcement provisions. At European level, CLP was being managed by ECHA and was included in the remit of the REACH CA meetings, renamed as Competent Authorities for REACH and CLP (CARACAL), and the work by both ECHA and European Commission began in earnest to incorporate CLP into their programmes of work.

CLP COMPETENCY AND TRAINING

While the Commission and ECHA were busy preparing for CLP during 2007/2008, the Authority too

was making plans; part of this was ensuring that our own expertise on classification and labelling was kept up to date. This was mostly achieved by engaging in the United Nations Sub-Committee of Experts on GHS (UNSCEGHS) sessions and its informal working groups, participating in the European Commission's REACH implementation projects and the European Councils Negotiations on CLP. The Authority staff engaged in this work, while small in number, were already classification and labelling experts, but the knowledge gained on GHS and subsequently CLP was to be a significant advantage when it came to passing this knowledge to their inspectorate colleagues at home.

Once the work on the CLP negotiations were completed in the latter half of 2008, along with the finalisation of the CLP guidance, the Authority's classification and labelling experts commenced training the chemicals inspectorate in 2009. For the CLP training, the REACH precedence again proved to be useful, as the training model developed by the Authority for CLP was based on one previously developed for REACH. The CLP training was of modular design, with seven modules delivered over six months. It was designed to slowly build up the CLP expertise of those who were not directly involved with the existing classification and labelling regime or CLP but who would become our CLP experts of the future.

This training plan developed into what we recognized as a *phased and tiered approach* to CLP competency. This took into consideration the different types of inspectors within the Authority and what their focus would be during an inspection. These training plans were developed in conjunction with the Authority enforcement strategy for CLP. In addition, ECHA's forum for exchange of information on enforcement, known as the "FORUM" is now actively engaged in CLP, having hosted its first "CLP train the trainer" event in January 2011 and incorporating CLP within its processes. The Authority anticipates that at a National level, enforcement of CLP will also be driven by the FORUM's projects on CLP in the future.

CLP HELPDESK

The CLP helpdesk within the Authority was formally established in January 2009, following the entry into force of CLP. It had in fact been running informally since June 2007 as the GHS helpdesk [2]. The only change internally was the change in its name from GHS to CLP *(Figure 1)*. The main advantage of its formal establishment was its inclusion in the support already established in ECHA via the network of national helpdesks for REACH and CLP, known as HelpNet. These tools have proven to be an invaluable resource to the national CLP helpdesk team both in giving and receiving information. During its first year of operation, CLP helpdesk queries were low in number. However, during 2010, over two hundred queries were processed, with more than one hundred in the last quarter of 2010 running up to the CLP classification and notification deadlines.

The Authority attended the first HelpNet meeting in February 2010. This twice yearly meeting is a good opportunity to meet ECHA staff and other Member State CLP helpdesk members, with whom the Authority's CLP helpdesk team have regular correspondence with via a tool known as the HelpEx. This online tool is used to post difficult CLP related questions and also to formulate ECHA's frequently asked questions (FAQs). Following similar processes already established for the REACH helpdesks, this system is a significant step forward in the interpretation of CLP and agreeing an approach on questions and answers. In addition to national helpdesk activities, the Authority's CLP helpdesk team participated extensively in the development of the ECHA CLP FAQ's during 2009 and 2010. This provided an excellent opportunity for improving and maintaining competency in CLP and also in assisting the attainment of a greater practical understanding of CLP.

EUROPEAN CHEMICALS AGENCY (ECHA) ENGAGEMENT

The Authority was involved in the development of the ECHA CLP introductory and classification criteria guidance from 2007, whose development at that time was part of the REACH implementation projects (RIPs). This proved to be a great opportunity for the Authority's classification and labelling experts to demonstrate and maintain their competency in CLP while gaining further practical experience. The Authority was involved in three of the four working groups and on a specialist experts group during what was known as the RIP 3.6 project. In more recent times, the Authority has participated in the development of the ECHA CLP labelling and packaging guidance and in updating the CLP criteria guidance, to take account of the proposed changes with the 2nd adaptation to technical progress (ATP) to CLP, most notably for the environmental hazards. Both sets of guidance are due to be published in 2011. In addition, the Authority also provides comments, as part of its ECHA Member State Competent Authority role, on Harmonized Classification and Labelling (CLH) proposals as they go through the consultation process.

EUROPEAN COUNCIL AND COMMISSION ENGAGEMENT

During 2007/2008, the Authority participated in the CLP Negotiations at Council, the legislative reviews of the 1st ATP and more recently, the 2nd ATP to CLP. The Authority participates at CARACAL and the Article 133 meetings ensuring that CLP is kept up to date with technical progress and scientific developments. It would appear that this "biennium cycle" of updating CLP will continue and this adds to the challenge of regulators and industry to keep up to date with CLP.

IRISH GOVERNMENT ENGAGEMENT

At a national level, the Authority was involved in the development of the Chemicals (Amendment) Act, 2010 (no. 32 of 2010) which was lead by the Irish Government's Department of Enterprise, Jobs and Innovation (DEJI). The Chemicals (Amendment) Act, 2010 put the necessary administrative and enforcement provisions for CLP in place in Ireland. This amendment was an update to the existing Chemicals Act 2008 (no.13 of 2008), which incorporated REACH. The 2008 Act was modelled on the Safety, Health and Welfare at Work Act, 2005 (no. 10 of 2005) to include consistency in the enforcement of the new direct acting chemical regulation and the existing Occupational Safety and Health (OSH) Directives. The Acts includes the appointment & powers of Inspectors and the level of fines and penalties. A summary conviction may result in a max of 5000 € fine or 12 months in prison, whereas a conviction on Indictment gives a fine of 3 000 000 € or 2 years in prison. There is also an option for a summary conviction to use a "fixed payment notice" of 2000 € which negates the requirement to go to court. In addition to the Chemicals Amendment Act, the Irish Government also recently published a Regulation under the Act to allow the use of English only on labels as required by Article 17.2 of the CLP Regulation. It is known as the Chemicals Act (CLP Regulation) Regulations 2011 (S.I no 102 of 2011) and came into effect on the 2nd March 2011.

AUTHORITY ENFORCEMENT AND CONTROLS

The Authority sees its primary role in CLP to provide information and advice to all companies, organisations and individuals. However, there are of course the necessary enforcement activities. The first national enforcement strategy for CLP was drawn up in 2010 following the first round of training completed at the end of 2009. CLP was incorporated into the existing REACH enforcement strategy within the Authority, which had been running since 2007. This programme included 1200 inspections during 2010. At the beginning of 2010, the Authority was not officially appointed as enforcement Authority for CLP, therefore the primary focus of the inspections undertaken during 2010 was to raise awareness and information gathering about CLP. In view of this, two specific questions were prepared that our inspectors asked on site.

The questions and the results are set out in *Table 1*.

Given our experience from the existing labelling and Safety Data Sheet (SDS) regime, the results for question 1 were as expected. At the face of it, the results for question 2 were initially surprising; however as the majority of Irish industry fall into the small and medium enterprise sector, the results would be in line with expectations. However, Irish industry did submit a significant amount of classification and labelling (C&L) notifications by the first deadline amounting to 3% of the total received by ECHA. Therefore, if Irish industry is taken as a small cohort to the rest of Europe, the statistics from our inspections hold up really well with the reality of what notifications were submitted by Irish industry.

For 2011, the Authority CLP strategy will be similar to its 2010 activities except that the number of inspections has increased to 1500. Again the proposed CLP questions will focus on the hazard labels and their consistency with the SDS and Classification and Labelling Notification requirements. In addition, the Authority intends to participate in the FORUM enforcement project on downstream users, including formulators. This is expected to include both REACH and CLP elements. It is also anticipated, now that the Authority is formally appointed as the enforcement Authority for CLP, it will move from awareness raising activities on CLP only, to include enforcement action, where required. The chemicals inspectorate responsible for enforcing CLP is located in eight different locations throughout Ireland. The Authority has a centralized database system for recording all inspection data regardless of location, known as GeoSmart. This makes collating the information from the inspections relatively easy.

CLP AWARENESS RAISING

The Authority started raising awareness on GHS in 2006, creating a GHS logo, running seminars, presentations, creating a website www.ghs.ie and a GHS helpdesk ghs@hsa.ie. Stakeholders were becoming familiar with the GHS term when the new acronym "CLP" emerged near the end of the negotiations

Table 1 | *Programme of Work 2010*

Question 1: Is hazard labelling information consistent with that provided in the SDS?	No action	Verbal advice	Written advice	Improvement notice	Prohibition notice
Result in %	44%	42%	13%	0%	0%
Question 2: Is company required to notify the Classification & Labelling of substances(s) which they manufacture or import in accordance with Article 40 of the Classification, Labelling & Packaging Regulations?	Yes			No	
Result in %	3%			97%	

2008. So although two years were spent promoting the term GHS, the Authority made a decision in January 2009 to switch from GHS to CLP for national awareness raising activities in order to distinguish the now *"direct acting European Regulation"* CLP from the *"United Nations International Convention"* that was GHS. This created its own difficulties when referring to CLP and GHS at the same time as it created confusion due to a misunderstanding of the relationship between the Regulation and UN convention. A similar situation had occurred in 2007, when confusion would occur on mention of both REACH and CLP. Today however, the fog of confusion appears to be lifting. Just like what happened with REACH and CLP by 2009, Industry now understand the links between CLP and GHS.

Awareness raising activities during 2009 focused on making industry familiar with the new terminology, classification criteria and labelling rules. In 2010 the focus was on the first CLP deadlines regarding classification and notification requirements. Four seminars and two webinars were hosted during this period, as well as taking every opportunity to be guest speakers at events lead by other stakeholder organisations. In terms of our seminars and webinars in 2010, we incorporated the changes to the label and the SDS together, as in practical terms, the label and SDS have to be considered and planned for as one. This approach proved to be very successful especially given the CLP influence on the new SDS regulation (www.hsa.ie/clp).

In 2009 the Authority published a successful CLP Brochure, which gave a broad overview of the CLP requirements. Then in 2010, in the run up to the classification and notification deadlines, the Authority circulated postcards and posters on CLP, placed advertisements in the national newspapers, published articles in trade magazines and the Authority newsletter. In addition, quarterly e-bulletins, stakeholder emails and website formed part of our CLP communications strategy. For 2011 creativity on communicating the CLP message against a backdrop of diminishing resources and budget constraints will be important.

UNITED NATIONS GHS

From 1998 to 2001, Dr Iona Pratt, (www.milieu.be/iona_pratt.html) working for the Authority at that time, chaired the International Labour Organization Working Group of Hazard Communication, within the framework of GHS. This subsequently developed into the UNSCEGHS, which the Authority has participated in since 2005. Our involvement since the beginning of GHS has certainly proven to be a great advantage when it came to the introduction of the GHS criteria into Europe, especially during the CLP negotiations for a number of reasons. Firstly, because we knew what was coming down the tracks and secondly, because we were directly involved from the beginning when the classification criteria and labelling rules were being decided so this ultimately helped to shape our own future. Although, a lot of the hard work in agreeing the classification criteria and labelling rules is complete at the UNSCEGHS forum, now that we have introduced this GHS criteria into Europe via CLP, our continued involvement at the UN GHS, either as individual national experts our collectively as a European Union, is crucially important to ensure that GHS is implemented around the world in a consistent manner. This is especially true as Europe, being one of the largest trading blocks to implement GHS first, so the world is watching to see how we get along. This is to insure that we attain the ultimate aim of having one global chemical hazard communication scheme. As an Authority, we remain committed to this work.

CONCLUSION

After more than five years of working behind the scenes, the Health and Safety Authority is ready as one of the Competent and Enforcement Authorities for CLP in Ireland. The publication of the Chemicals Amendment Act 2010 may have marked the Authority's official appointment, *i.e.* the beginning for CLP, but it also marked the end of the first implementation process for the Authority and the inclusion of CLP into its programme of work. CLP is now part of the Authority's remit, along with a long list of other chemical and occupational safety and health legislation administered and enforced by the Authority. The CLP implementation process, having closely followed that of REACH, certainly brought with it advantages in its implementation both within the Authority and within Europe generally, especially in following the processes already established by REACH. The disadvantage of CLP and REACH being implemented together was that it brought certain challenges to the Authority, in particular issues around resources, training and awareness raising initiatives. As it transpired, it took time to prepare for CLP, time to absorb what CLP was about and time to disseminate the CLP message.

Given the added complexity of the phased transitional period of CLP, there are obvious challenges with having a dual classification and labelling system for a number of years and having part of CLP operational and part still to be implemented fully. In addition, the international dimension that is GHS will bring with it an ever changing regime, with updates to CLP very two years. This process is familiar to colleagues responsible for implementing changes in ADR policy, but new for those responsible for CLP policy. In time, the changes to GHS and therefore CLP will reduce considerably as the rest of the globe follow the European lead, *i.e.* focus more on implementing GHS rather than changing its content leading to the ultimate goal of having one global hazard communication system. Another challenge faced by the Authority relates to the work generated by CLP from the European Commission, ECHA and the United Nations, *i.e.* how will we attain a

balance with these outside obligations alongside our own national responsibilities and workloads?

Looking ahead, CLP is now operational and incorporated into the Authority's strategy whose goal is to promote the safe and sustainable management of chemicals. To support this, 1500 inspections will be undertaken in 2011, focusing on both hazard labels and notification obligations The Authority will continue to develop the CLP enforcement strategy, work on FORUM projects incorporating CLP, increase the number of inspections looking at chemicals, focus on high risk sectors and high risk chemicals and continue to improve our inspectorate knowledge on CLP. In addition, the classification and labelling experts within the Authority will prepare for the next transitional phase regarding classification of mixtures under CLP, keep up to date with UNGHS activities, implement future ATP's to CLP and disseminate that message outwards among our inspectorate and industry. In essence, a lot done and a lot more to do!

Conflict of interest statement

There are no potential conflicts of interest or any financial or personal relationships with other people or organizations that could inappropriately bias conduct and findings of this study.

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The National helpdesk activity in Italy: report of the first year (2010)

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Summary. National CLP heldpesk is a service established in every Member State providing advice to companies and other stakeholders on the obligations they may have under CLP. In Italy the national helpdesk is located into the Center of Chemical Substances (CSC) in the National Institute of Health. Helpdesks will provide with wide ranging information on the provisions of CLP. They will also advice on the responsibilities the suppliers of chemical substances have to fulfill under these Regulations. Too specific questions cannot be answered as the aim of the helpdesk is to give a general interpretation of CLP principles and requirements instead of solving tailor made problems.

Key words: chemicals, classification, labelling, helpdesk.

Riassunto *(Relazione sulle attività dell'helpdesk CLP in Italia per l'anno 2010)*. L'helpdesk nazionale è un servizio stabilito presso ogni Stato Membro per fornire supporto alle ditte e agli altri soggetti interessati sugli obblighi del CLP. In Italia l'helpdesk nazionale è stabilito presso il Centro Nazionale Sostanze Chimiche (CSC) dell'Istituto Superiore di Sanità. L'helpdesk fornisce un ampio ventaglio di informazioni sui requisiti del Regolamento CLP e consiglia in merito alle responsabilità dei fornitori di prodotti chimici nel soddisfare i requisiti del CLP. Le risposte ai quesiti non risolvono le esigenze troppo specifiche dei singoli richiedenti. Lo scopo dell'helpdesk è quello di fornire interpretazioni di applicabilità generale pur riferite a casi specifici.

Parole chiave: sostanze chimiche, classificazione, etichette, helpdesk.

INTRODUCTION

In the application of Article 44 of Regulation (EC) 1272/2008 [1] "regarding classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and amending the Regulation (EC) no. 1907/2006" [2], the Competent Authority has charged the National Center of Chemical Substances (CSC) of Istituto Superiore di Sanità (ISS) to set up a helpdesk as technical assistance service and as support in applying the Regulation.

The Ministry of Health has to formally delegate through an actuator Decree the Institute's CSC, which has already been providing this service.

Such activity is meant to support the manufacturers, importers, distributors downstream users and simple users in charge of applying the Regulation.

The majority of the questions concerns CLP's transitional provisions. It is in fact important to underline that the CLP Regulation has become effective on January 20, 2009. Nonetheless not all the provisions are immediately mandatory, since the transitional ones (Article 61) set two different dates as for classification, communication of danger and packaging of dangerous substances and mixtures, which are December 1, 2010 and June 1, 2017.

Although the Regulation has specified other characters to solve questions not regarding CLP (application of the Regulation 1907/2006 REACH, firms' duties on registration, evaluation, authorization and restriction) the helpdesk provides in any case assistance in identifying the institutional referential figure.

The analogous instrument in the European perspective is helpex. It is constituted by national REACH helpdesk, CLP helpdesk and European Chemicals Agency (ECHA) and is in charge of providing consistent opinions to producers, importers, simple users and others concerned figures in order to make easier a proper and full application of both Regulations 1907/2006 and 1272/2008.

This paper is meant to identify the actors somehow involved in the application of the CLP Regulation, the typology of the most frequently asked questions, the needed interpretations for a correct application and the operational modalities to convey information to ECHA.

One of the main helpdesk's activities will be to spread the information in order to ease firms' access, with particular attention given to small and medium enterprises (SME) and "Microenterprises", to technical or scientific innovations which might change the modality for classification and labelling of substances and mixtures, as suggested by CLP Regulation's Article 15.

The helpdesk instrument turns out to be appropriate and effective especially regarding the human

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resources and the technical and scientific competences that CSC has invested in its organization.

According to CLP Article 44, a helpdesk for companies has been set at the ISS National Center for Chemical Substances (CSC) in order to provide information on CLP requirements.

The CSC has been carrying out – in the national, European and international field – technical and scientific activities on chemical substances and mixtures, supporting the Ministry of Health, which has been appointed as Competent Authority for the implementation of both REACH and CLP Regulations.

The CSC is assisted by a group of specialists to develop the activities of CLP helpdesk. The attendance at Helpnet's meetings is also guaranteed. During these meetings Member States and the Agency discuss together issues and questions that either require close examination or might be subject to different interpretations. Among the Helpnet activity's results we would like to remember the Frequently Asked Questions (FAQ) publication.

The Agency's helpdesk has the duty to coordinate the activities of all the national helpdesks and represents a second level helpdesk for major issues, or for questions which have dubious interpretation.

DESCRIPTION OF RESULTS

During 2010, national helpdesk's activity has experienced, month after month, a raise in the requests from companies and stakeholders interested in the application of Regulation 1272/2008. In fact, December 1st, 2010 has represented an important day, as it was the deadline for the application of the new classification and labeling system to substances.

In addition to that, also the new and the revised entries reported in the 1st adaptation to technical progress had to be applied at the same date.

A database has been arranged in order to better organize the helpdesk management, and then enriched with users' questions. Every question has been linked to 1 or 2 key words in order to index the topics and provide homogeneous answers to similar questions. The key words identified so far are described in *Table 1*.

The number of questions sent to the helpdesk in 2010 has increased month by month, and reached its peak in November *(*see *Figure 1)*.

The typology of applicants is shown in *Figure 2*. They are manufacturers, importers, consultants, downstream users and "not defined" (*e.g.* simple users). It can be pointed out that in Italy many small enterprises are supported by consultants in order to fulfill the requirements of CLP. We can see from the diagram a great difference between the number of importers

Table 1 | *Helpdesk database: numbers and percentages of the questions for each key word*

Number	%	Key words	Number	%	Key words
47	7	Notification	10	< 1.8	CMR substances
39	6.5	Safety Data Sheet	9	< 1.8	Language
39	6.5	Labeling	9	< 1.8	UVCB substances
37	6.1	Classification	9	<1.8	Annex VI and I ATP
32	5.3	Hazard pictogram	8	< 1.8	Acute toxicity test
29	4.8	Hazard statement	8	< 1.8	Criteria for STOT
29	4.8	Placing on the market	8	< 1.8	Alloys
30	4.9	Corrosion	8	< 1.8	Substances and dilution
27	4.5	Mixtures	8	< 1.8	Substances off the shelves
30	4.9	Self classification	7	< 1.8	*In vitro* medical devices
22	3.6	Precautionary statement	7	< 1.8	Polymers
21	3.4	Explosives	6	< 1.8	Viscosity
17	2.8	Medicinal products	4	< 1.8	Disposal storage
17	2.8	Variable composition	5	< 1.8	C&L Inventory
15	2.4	CAS name or IUPAC name	4	< 1.8	Importers
12	1.9	Foodstuffs	2	< 1.8	Re-packaging
11	1.8	Risk assessment at work	2	< 1.8	Liquid gas
12	1.9	REACH related	1	< 1.8	ISO Standard
10	< 1.8	Packaging			

CAS - Chemical Abstracts Service;
CMR - Carcinogenic, Mutagenic or Toxic to Reproduction;
ISO - International Standard Organization;
IUPAC - International Union of Pure and Applied Chemistry;
STOT - Specific Target Organ Toxicity;
UVCB - Substances of Unknown or Variable Composition.

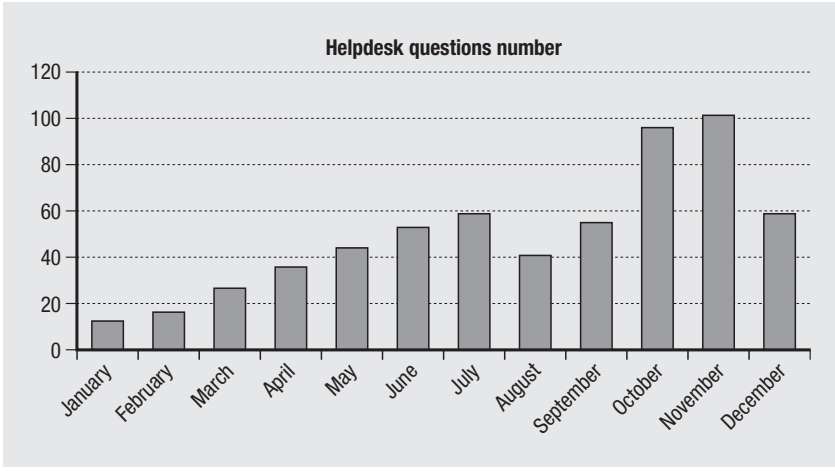

Fig. 1 | *Helpdesk questions distribution by month (2010).*

and manufacturers. As for Regulation 1272/2008, it is important to highlight the importer's figure, which plays a leading role in the supplying chain, since he is the one responsible for the introduction of products (substances, mixtures and items) in the European market; the importer is in fact bound to provide users with all the needed information regarding consumers and workers' safety and protection. For this reason, the CLP Regulation sees the helpdesk's start up especially as a support to SME (Article 44).

It is then understandable that the majority of the questions come from such users. Instead, downstream users – workers or employers – refer to the helpdesk for questions regarding how to fill out the Safety Data Sheets (SDS) forms or how to update the evaluations on chemical risk, as requested by Legislative Decree 81/2008 [3] on safety and health protection in work environments.

In *Figure 3* the distribution of total questions *vs* key words is shown and in *Figure 4* the percentage levels with relation to the key words.

In *Table 1* the key words used to group together the issues presented and considered by the helpdesk are shown. From this table we can notice that the majority of the issues concerns the fulfillment of obligations which have become compulsory since December 1st, 2010. These are the modalities of substances' notification to the database at ECHA, labels' elements, classifications criteria for substances and mixtures, new definitions regarding the introduction of substances into the market and new indications and pictographs which replaced the old sentences and symbols of danger. Great attention has been also given to the relapse of the new Regulation concerning the legislation on safety in working environments.

This paper concerns specific questions which have appeared more frequently and which have drawn the attention of the international political scene. Some of the following questions/answers come from the helpnet platform and the final ECHA view is reported.

Otherwise other examples come from the Italian helpdesk and reflect the current view of experts in the CLP regulation issues.

Classification physical and health hazards: comparison between DSD and CLP

A substance does not meet the classification criteria under the Dangerous Substances Directive (DSD) [4], but it could be classified under CLP; in fact for a range of hazard, the classification criteria have changed, *e.g.* for many physical hazards where the test methods which determine the classification criteria are often different from those of DSD. For other hazards, the applicable concentration limits for taking into account the classification of its

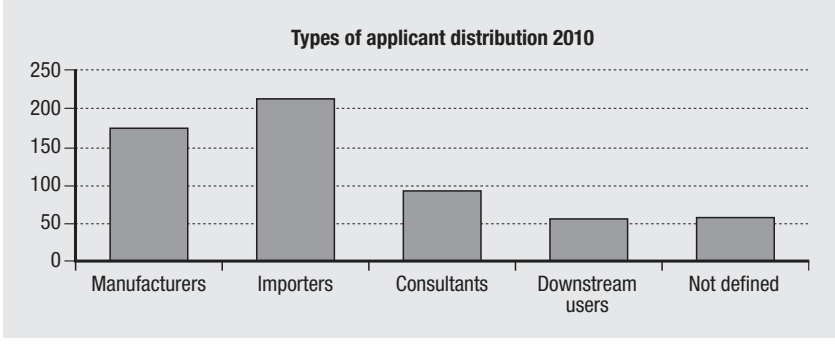

Fig. 2 | *Types of applicants.*

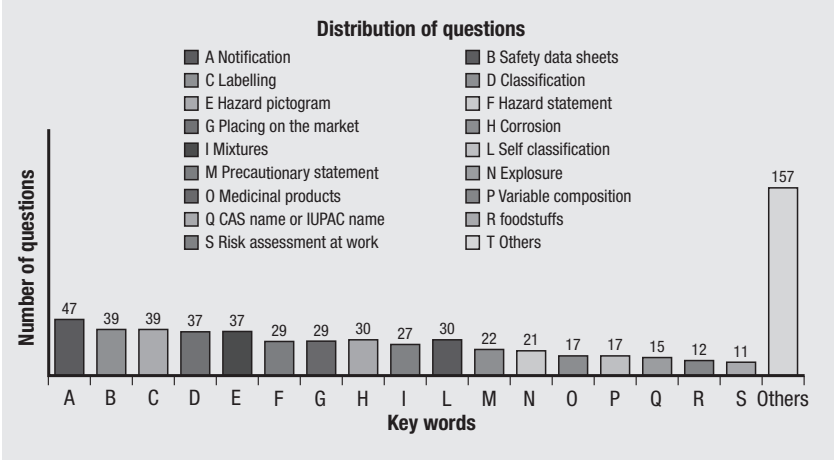

Fig. 3 | *Distribution of questions* vs *key words.*

constituents, additives and impurities contained in the substance have changed, *e.g.* for the irritation and corrosive hazards. This means that in the cases where there is no reliable test information on the substance as a whole and the bridging principles cannot be applied, the use of the calculation rules with concentration limits may lead to a classification under CLP, even though the same substance was not classified under DSD (this information is also available in *ECHA Guidelines* [5]).

May a supplier use data which is available in open literature or for internet or in online databases for the purpose of physical hazards classification under CLP?

He may, the data is reliable and adequate for the purpose of hazard classification.

The physical hazards of substances and mixtures should be determined through testing based on the methods of standard referred to in part 2 annex I of CLP. These methods can be found for example in the UN Manual of test, and criteria seen at website of UNECE [7]. These criteria are normally used to classify substances and mixtures for transport, however testing is not mandatory in cases where adequate and reliable information from reference literature or databases is already available, and where the substance to be classified and the substance described in the reference are comparable with regard to homogeneity, impurities, particle sizes etc.

Open literature or databases often use secondary data sources. When such data is used, the original source should be cited and checked by an expert. This check should make sure that there is sufficient documentation to assess the suitability of the test used, and that the test was carried out using an acceptable level of quality assurance.

Where the criteria cannot be applied directly to available identified information, the weight of evidence determination using expert judgment shall be applied in accordance with Article 9 of CLP. For the weight of evidence determination, all available information is considered together, such as the results of suitable *in vitro* tests, relevant animal data, information from the application of the category approach, QSAR results, human experience (occupational data) etc. the quality and consistency of the data shall be given appropriate weight. For the purpose of classification for health hazards, established hazardous effects seen in appropriate animal studies

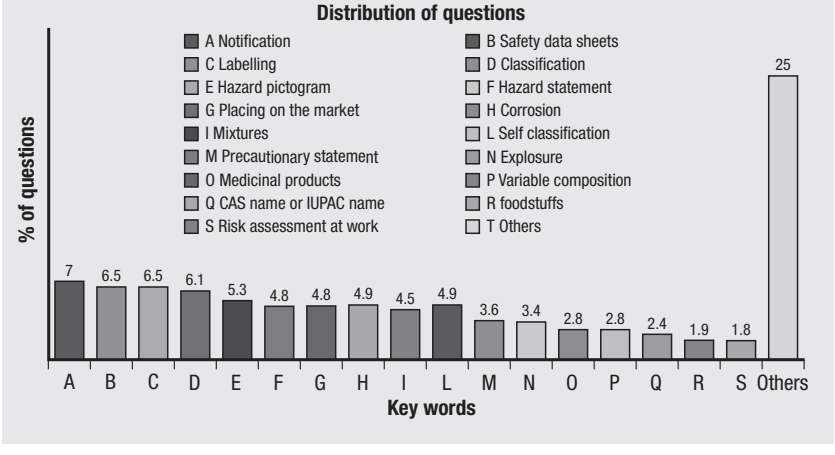

Fig. 4 | *Percentage of questions* vs *key words. "Others" is the total of all key words % lower than 1.8.*

or from human experience that are consistent with the criteria for classification shall normally justify classification. Where evidence is available from both humans and animals and there is a conflict between the findings, the quality and reliability of the evidence from both sources shall be evaluated in order to resolve the question of classification. Generally data on humans shall have precedence over other data. At this moment the helpdesk has not requested questions for environmental hazards.

The meaning of "placing on the market"

Placing a substance or mixture on the market under CLP means supplying or making it available to third parties, whether in return for payment or free of charge within the territory of the EU Member States and those European Economic Area – European Free Trade Association (EEA-EFTA) countries which have implemented the CLP Regulation.

In addition, import, defined as the physical introduction of a substance or mixture into the customs territory of the EU and those EEA-EFTA countries which have implemented the CLP Regulation, is deemed to be placing on the market.

"Placing on the market" and notification

In relation to notification, placing on the market is a pre-condition: substances which are referred to in CLP Article 39 have to be notified to the C&L Inventory if they are placed on the market. However, no notification is required if the information mentioned under CLP Article 40 has already been provided as part of a previous registration or notification by the same notifier.

Substances in stock on 1 December 2010 have to be notified

Substances that are "in stock" on 1 December 2010 are not considered to be "placed on the market" on that day, and therefore will not have to be notified by 3 January 2011. However, when placed on the market, they will have to be notified within 1 month after their placing on the market by their manufacturer or importer. A distributor who takes substances off the shelves where they have been stored for a while, in order to sell them to others, will not have to notify to the C&L Inventory as this obligation affects only manufacturers and importers.

Who must do notification?

Any manufacturer or importer, or group of manufacturers or importers (hereinafter referred to as "the notifier(s)"), who places on the market a substance referred to in Article 39, shall notify to the Agency the following information in order for it to be included in the inventory referred to in Article 42.

Deadline notification

The notification deadline is dependent on the date on which the substance is placed on the market. When a substance is placed on the market on 1 December 2010, it must be notified to the C&L Inventory within 1 month, *i.e.* the notification deadline is 3 January 2011. If a substance is placed on the market before 1 December 2010, *e.g.* on 10 October 2010, and placing on the market is done again on 17 January 2011, the notification will be due by 17 February 2011.

In relation to import, as of 1 December 2010, the 1-month timeline is counted from the day when the substance or mixture is physically introduced into the customs territory of the EU Member States and those EEA-EFTA countries which have implemented the CLP Regulation.

Labeling and deadline

If the substance or mixture classified, labeled and packaged in line with Directive 67/548/EEC (Dangerous Substances Directive, DSD) or, in case of mixtures, Directive 1999/45/EC (Dangerous Preparations Directive, DPD) [6], has already been placed on the market before 1 December 2010 or 1 June 2015 respectively, the substance or mixture which is still in stock does not have to be relabeled and repackaged in accordance with the CLP rules by the supplier before 1 December 2012 or 1 June 2017 respectively.

It is pointed out that under certain conditions, substances manufactured before 1 December 2010 and stored in the manufacturer's warehouse after 1 December 2010 and mixtures prepared before 1 June 2015 and stored in a formulator's warehouse after 1 June 2015 can benefit from the transitional arrangements provided in Article 61(4). This would normally be the case where the transfer of ownership of the substance or mixture has taken place before 1 December 2010 or 1 June 2015 respectively, although the substance or mixture does still remain in the manufacturer's or formulator's warehouse, *i.e.* no physical hand-over of the substance or mixture.

It is not allowed to use label elements according to Directive 67/548/EEC (DSD) or 1999/45/EC (DPD) [6] together with elements according to the CLP Regulation on the same label as this would lead to confusion on the market and hamper the transition to the CLP classification and labeling system. Only one labeling system shall be applied on any label; which one to choose will depend on the timing in relation to the transitional deadlines of 1 December 2010 and 1 June 2015. In case you decide to already classify, label and package a substance according to the CLP rules before 1 December 2010 or a mixture before 1 June 2015, you must not use any labeling elements in accordance with DSD or DPD respectively.

Safety Data Sheet (SDS)

SDS is the most important communication tool within the supply chain of substances or mixtures. The supplier of these substances or mixtures shall provide the recipient with a safety data sheet in accordance with new Regulation (EC) 453/2010 [8] that updates Annex II of Regulation 1907/2006. Many suppliers shall known the amendments until 2015 in

the classification for substances and mixture in the SDS as shown in ECHA Guidelines [9]:
- After 1st December 2010 and until 1st June 2015 both DSD and CLP classification shall be provided in SDS for classification of substances on their own and according to DPD for mixtures containing these substances;
- Until 1st June 2015 the classification of a mixture according to DPD shall be provided in the SDS; if a mixture is classified, labeled and packaged in according to CLP, the CLP classification shall appear on the SDS alongside the classification based on the DPD;
- From 1st June 2015, substance and mixture classifications according to CLP shall be provided in the SDS. From this date the old legislation (DSD and DPD) will be repealed, and classifications according to DSD or DPD will no longer be allowed.
- From 1st June 2015 the SDS shall provide in accordance with annex II of Regulation (EC) 453/2010.

Questions about the relapse of the application regarding the EC Regulation 1272/2008 on Legislative Decree 81/2008 (health safety at workplaces)

Professional and industrial users have no obligations under CLP because they are considered to be end users of the substances and mixtures on the market. Examples of professional users are cleaning personnel, painters, or craftsmen who use paints, lime or cleaning agents in the context of their professional activity. On the contrary, formulators of mixtures are not considered as end users, but rather as downstream users of substances and mixtures.

Professional and industrial end users are required to respect the information on the label and on the SDS supplied to them. Further to this, they have to comply with the downstream users obligations set out in title V of REACH on the safe handling and use of substances and mixtures.

It is important to note that end users established within the EU who are supplied with substances or mixtures by an actor outside the EU, are considered to be importers under CLP. This means that they have the obligation to classify, label and package these substances and mixtures and to notify relevant substances information to C&L Inventory.

Especially, clarifications are required on the new prescription for the SDS's drafting, and the new criteria for the classification of dangerous substances and mixtures, given the presence of new grades of danger, which could involve changes in the risk estimation.

However, we would like to underline that when the employer, given the e-SDS, is bound to connect some exposure's scenarios with the use of chemical substances, he will have the chance to use the information given in the SDS to make the risk estimation under the Articles 223 and 236 of Legislative Decree 81/2008 as last amended. The exposure scenarios in fact, when available, represent useful sources of information that the employer has to rely to for the estimation of the risk.

Furthermore, if the employer cannot apply the uses and sceneries shown in the REACH Regulation to his workplace, he is then bound to communicate his own scenario either to the responsible for the introduction to the market (provider) or directly to the ECHA.

To cap it all we would like to remember that the provider must communicate:

I. a SDS to the recipient of the mixture or substance (downstream users or to the employer), under REACH Article 31, as modified by UE 453/2010 Regulation, when:
   a) the substance or the mixture meets the criteria for classification as dangerous;
   b) the substances are persistent, bioaccumulative and toxic (PBT) and very persistent and very bioaccumulative (vPvB);
   c) a substance is included in Annex XIV (Article 59 REACH), as substances meeting the criteria for classification as CMR Category 1 or 2, or persistent, bioaccumulative and toxic in accordance with the criteria set out in Annex XIII;
   d) the substances are very persistent and very bioaccumulative in accordance with the criteria set out in Annex XIII.
II. To the recipient of articles containing a substance referable to point sub. I.c. (with a concentration higher than 0.1% weight/weight), enough information to allow a safe use of the article and, at least, the name of the substance.

In order to make a complete and correct estimation of the risk, the employer must also ask the provider a SDS for mixtures classified as non dangerous but containing dangerous substances in concentration lower than the one required for the classification duty, under REACH Article 31 paragraph 2. He will anyways have to ask for information about substances (being them actual substances or part of a mixture) concerning REACH field of application, under REACH Article 32.

The purpose of the Italian helpdesk is to propose to industry an overview of the critical documents needed for the implementation of CLP processes. A website has been recently implementing for this reason. We believe this will greatly improve the visibility and usage of information (guidance, manuals, fact sheets, etc.).

Conflict of interest statement

There are neither potential conflicts of interest nor financial or personal relationships with other people or organizations that could inappropriately bias the conduct and findings of this study.

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